

**DECLARATION OF CONFORMITY (EN)  
КЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ (BG)  
IZJAVA O SUKLADNOSTI (HR)  
PROHLÁŠENÍ O SHODĚ (CS)  
OVERENSSTEMMELSESERKLÆRING (DA)**

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REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL DEVICES  
РЕГЛАМЕНТ (ЕС) 2017/745 НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ И НА СЪВЕТА ЗА МЕДИЦИНСКИТЕ ИЗДЕЛИЯ  
UREDBA (EU) 2017/745 EUROPSKOG PARLAMENTA I VIJEĆA O MEDICINSKIM PROIZVODIMA  
NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2017/745 O ZDRAVOTNICKÝCH PROSTŘEDCÍCH  
EUROPA-PARLAMENTETS OG RÅDETS FORORDNING (EU) 2017/745 OM MEDICINSK Udstyr

**Manufacturer:** LM-Instruments Oy  
**Производител:** SRN: FI-MF-000006705  
**Proizvođač:** Norrbyn rantatie 8  
**Výrobce:** 21600 Parainen  
**Producent:** Finland  
Tel. +358 2 4546 400

This declaration of conformity is under the sole responsibility of LM-Instruments Oy. Herewith we declare products listed in the appendix A comply with the regulations (EU) 2017/745 for medical devices by application of harmonized standards EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 and EN ISO 15223-1:2021. The products are classified as Medical Devices, Class I.

Настоящата декларация за съответствие е под изключителната отговорност на LM-Instruments Oy. С настоящото декларираме, че продуктите, изброени в приложение А, отговарят на Регламент (ЕС) 2017/745 за медицинските изделия чрез прилагане на хармонизирани стандарти БДС EN ISO 13485:2016, БДС EN ISO 14971:2019, БДС EN ISO 17664-1:2021, EN ISO 10993-18:2020 и БДС EN ISO 15223-1:2021. Продуктите са класифицирани като медицински изделия от клас I.

Ova izjava o sukladnosti pod isključivom je odgovornošću društva LM-Instruments Oy. Ovime izjavljujemo da su proizvodi navedeni u prilogu A sukladni s uredbom (EU) 2017/745 o medicinskim proizvodima, uz primjenu usklađenih normi EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 i EN ISO 15223-1:2021. Proizvodi se mogu svrstati u medicinske proizvode klase I.

Za toto prohlášení o shodě nese výhradní odpovědnost společnost LM-Instruments Oy. Tímto prohlašujeme, že produkty uvedené v příloze A splňují předpisy (EU) 2017/745 pro zdravotnické prostředky s využitím harmonizovaných norem EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 a EN ISO 15223-1:2021. Tyto produkty jsou klasifikovány jako zdravotnické prostředky třídy I.

Denne overensstemmelseserklæring er udelukkende LM-Instruments Oy's ansvar. Hermed erklærer vi, at de produkter, der er anført i bilag A, er i overensstemmelse med forordning (EU) 2017/745 om medicinsk udstyr ved anvendelse af de harmoniserede standarder EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 og EN ISO 15223-1:2021. Produkterne er klassificeret som medicinsk udstyr, Klasse I.

**CONFORMITEITSVERKLARING (NL)  
VASTAVUSDEKLARATSIOON (ET)  
VAATIMUSTENMUKAISUUSVAKUUTUS (FI)  
DÉCLARATION DE CONFORMITÉ (FR)  
KONFORMITÄTSERKLÄRUNG (DE)**

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VERORDENING (EU) 2017/745 VAN HET EUROPEES PARLEMENT EN DE RAAD BETREFFENDE MEDISCHE HULPMIDDELEN

EUROOPA PARLAMENDI JA NÕUKOGU MEDITSIIINISEADMETE MÄÄRUS (EL) 2017/745

EUROOPAN PARLAMENTIN JA NEUVOSTON ASETUS (EU) 2017/745 LÄÄKINNÄLLISISTÄ LAITTEISTA

REGLEMENT (UE) 2017/745 DU PARLEMENT EUROPEEN ET DU CONSEIL RELATIF AUX DISPOSITIFS MEDICAUX

VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES ÜBER MEDIZINPRODUKTE

**Fabrikant:** LM-Instruments Oy  
**Tootja:** SRN: FI-MF-000006705  
**Valmistaja:** Norrbyn rantatie 8  
**Fabricant:** 21600 Parainen  
**Hersteller:** Finland  
Tel. +358 2 4546 400

Deze conformiteitsverklaring valt onder de uitsluitende verantwoordelijkheid van LM-Instruments Oy. We verklaren hierbij dat de producten die in bijlage A worden vermeld aan de Verordening (EU) 2017/745 betreffende medische hulpmiddelen voldoen door de toepassing van de geharmoniseerde normen EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020, EN ISO 10993-18:2020 en EN ISO 15223-1:2021. De producten zijn geclassificeerd als medische hulpmiddelen van klasse I.

See vastavusdeklaratsioon kehtib LM-Instruments Oy ainuvastutusel. Käesolevaga kinnitame, et lisas A loetletud tooted vastavad meditsiiniseadmeid käsitlevale määrusele (EL) 2017/745, kohaldades harmoneeritud standardeid EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 ja EN ISO 15223-1:2021. Tooted on klassifitseeritud meditsiiniseadmetena, klass I.

Tämä vaatimustenmukaisuusvakuutus annetaan LM-Instruments Oy:n yksinomaisella vastuulla. Vakuutamme täten, että liitteessä A luetellut tuotteet ovat lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 vaatimusten mukaisia sovellettaessa harmonisoituja standardeja EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 ja EN ISO 15223-1:2021. Nämä tuotteet on luokiteltu luokan I lääkinnällisiksi laitteiksi.

Cette déclaration de conformité est sous la seule responsabilité de LM-Instruments Oy. Par la présente, nous déclarons que les produits énumérés dans l'annexe A sont conformes au règlement (UE) 2017/745 relatif aux dispositifs médicaux en application des normes harmonisées EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 et EN ISO 15223-1:2021. Les produits sont considérés comme étant des dispositifs médicaux de classe I.

Diese Konformitätserklärung unterliegt der alleinigen Verantwortung von LM-Instruments Oy. Hiermit erklären wir, dass die in Anhang A aufgeführten Produkte den Verordnungen (EU) 2017/745 für Medizinprodukte durch Anwendung der abgestimmten Normen EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 und EN ISO 15223-1:2021 entsprechen. Die Produkte sind als Medizinprodukte der Klasse I klassifiziert.



**ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ (EL)  
MEGFELELŐSÉGI NYILATKOZAT (HU)  
DICHIARAZIONE DI CONFORMITÀ (IT)  
ATBILSTĪBAS DEKLARĀCIJA (LV)  
ATITIKTIES DEKLARACIJA (LT)**

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**ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 ΤΟΥ ΕΥΡΩΠΑΪΚΟΥ ΚΟΙΝΟΒΟΥΛΙΟΥ ΚΑΙ ΤΟΥ ΣΥΜΒΟΥΛΙΟΥ ΓΙΑ ΤΑ ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΑ ΠΡΟΪΟΝΤΑ**

**AZ EURÓPAI PARLAMENT ÉS TANÁCS ORVOSTECHNIKAI ESZKÖZÖKRE VONATKOZÓ (EU) 2017/745-ÖS RENDELETE**

**REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO SUI DISPOSITIVI MEDICI  
EIROPAS PARLAMENTA UN PADOMES REGULA (ES) 2017/745, KAS ATTIECAS UZ MEDICĪNISKĀM IERĪCĒM  
EUROPOS PARLAMENTO IR TARYBOS REGLAMENTAS (ES) 2017/745 DĖL MEDICINOS PRIEMONIŲ**

|                       |                          |
|-----------------------|--------------------------|
| <b>Κατασκευαστής:</b> | <b>LM-Instruments Oy</b> |
| <b>Gyártó:</b>        | SRN: FI-MF-000006705     |
| <b>Produttore:</b>    | Norrbyn rantatie 8       |
| <b>Ražotājs:</b>      | 21600 Parainen           |
| <b>Gamintojas:</b>    | Finland                  |
|                       | Tel. +358 2 4546 400     |

Η παρούσα δήλωση συμμόρφωσης υπόκειται στην αποκλειστική ευθύνη της LM-Instruments Oy. Δια του παρόντος, δηλώνουμε ότι τα προϊόντα που αναφέρονται στο παράρτημα Α συμμορφώνονται με τους κανονισμούς (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα με την εφαρμογή των εναρμονισμένων προτύπων EN ISO 13485: 2016, EN ISO 14971: 2019, EN ISO 17664-1: 2021, EN ISO 10993-18:2020 και EN ISO 15223 -1: 2021. Τα προϊόντα ταξινομούνται ως Ιατροτεχνολογικά προϊόντα, Κατηγορίας Ι.

Ez a megfelelőségi nyilatkozat az LM-Instruments Oy kizárólagos felelőssége alá tartozik. Kijelentjük, hogy az EN ISO 13485:2016, az EN ISO 14971:2019, az EN ISO 17664-1:2021, EN ISO 10993-18:2020 és az EN ISO 15223-1:2021 harmonizált szabvány alkalmazásával az A függelékben felsorolt termékek megfelelnek az orvostechikai eszközökről szóló (EU) 2017/745 rendeletnek. A termékek I. osztályú orvostechikai eszköz minősítésűek.

Questa dichiarazione di conformità è sotto la sola responsabilità di LM-Instruments Oy. Con la presente dichiariamo che i prodotti elencati nell'appendice A sono conformi ai regolamenti (UE) 2017/745 per i dispositivi medici in applicazione degli standard armonizzati EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 e EN ISO 15223-1:2021. I prodotti sono classificati come Dispositivi medici, Classe I.

Par šo atbilstības deklarāciju atbildīgs ir tikai uzņēmums LM-Instruments Oy. Ar šo mēs apliecinām, ka A pielikumā norādītie produkti atbilst prasībām saskaņā ar Regulu (ES) 2017/745 par medicīniskajām ierīcēm, lietojot saskaņotos standartus EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 un EN ISO 15223-1:2021. Šie produkti ir klasificēti kā I klases medicīniskās ierīces.

Už šią atitikties deklaraciją atsako tik „LM-Instruments Oy“. Šiuo dokumentu deklaruojame, kad A priede išvardyti gaminiai atitinka reglamentą (ES) 2017/745 dėl medicinos priemonių, vadovaujantis darniaisiais standartais EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 ir EN ISO 15223-1:2021. Gaminiai klasifikuojami kaip I klasės medicinos priemonės.

**DEKLARACJA ZGODNOŚCI (PL)**  
**DECLARAÇÃO DE CONFORMIDADE (PT)**  
**DECLARAȚIE DE CONFORMITATE (RO)**  
**VYHLÁSENIE O ZHODE (SK)**

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**ROZPORZĄDZENIE PARLAMENTU EUROPEJSKIEGO I RADY (UE) 2017/745 W SPRAWIE WYROBÓW MEDYCZNYCH**

**REGULAMENTO (UE) 2017/745 DO PARLAMENTO EUROPEU E DO CONSELHO SOBRE DISPOSITIVOS MÉDICOS**

**REGULAMENTUL (UE) 2017/745 AL PARLAMENTULUI EUROPEAN ȘI AL CONSILIULUI PRIVIND DISPOZITIVELE MEDICALE**

**NARIADENIE (EÚ) 2017/745 EURÓPSKEHO PARLAMENTU A RADY O ZDRAVOTNÍCKYCH ZARIADENIACH**

**Producent:** LM-Instruments Oy  
**Fabricante:** SRN: FI-MF-000006705  
**Producător:** Norrbyn rantatie 8  
**Výrobca:** 21600 Parainen  
**Proizvajalec:** Finland  
Tel. +358 2 4546 400

Wyłączną odpowiedzialność za niniejszą deklarację zgodności ponosi LM-Instruments Oy. Niniejszym deklarujemy, że produkty wymienione w załączniku A są zgodne z wymogami rozporządzenia (UE) 2017/745 dotyczącego urządzeń medycznych dzięki zastosowaniu zharmonizowanych norm EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 oraz EN ISO 15223-1:2021. Produkty są sklasyfikowane jako wyroby medyczne klasy I.

A presente declaração de conformidade é da exclusiva responsabilidade da LM-Instruments Oy. Pela presente, declaramos que os produtos descritos no anexo A cumprem os regulamentos (UE) 2017/745 relativos a dispositivos médicos através da aplicação das normas harmonizadas EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 e EN ISO 15223-1:2021. Os produtos estão classificados como Dispositivos Médicos, Classe I.

Prezenta declarație de conformitate este dată sub responsabilitatea exclusivă a LM-Instruments Oy. Declarăm prin prezenta că produsele enumerate în anexa A respectă Regulamentul (UE) 2017/745 privind dispozitivele medicale prin aplicarea standardelor armonizate EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 și EN ISO 15223-1:2021. Produsele sunt clasificate ca dispozitive medicale Clasa I.

Za toto vyhlásenie o zhode nesie výhradnú zodpovednosť spoločnosť LM-Instruments Oy. Týmto vyhlasujeme, že produkty uvedené v prílohe A sú v súlade s nariadením (EÚ) 2017/745 o zdravotníckych pomôckach uplatnením harmonizovaných noriem EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 a EN ISO 15223-1:2021. Produkty sú klasifikované ako zdravotnícke pomôcky triedy I



**IZJAVA O SKLADNOSTI (SL)**  
**DECLARACIÓN DE CONFORMIDAD (ES)**  
**FÖRSÄKRAN OM ÖVERENSSTÄMMELSE (SV)**

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UREDBA (EU) 2017/745 EVROPSKEGA PARLAMENTA IN SVETA O MEDICINSKIH PRIPOMOČKIH  
REGLAMENTO DE DISPOSITIVOS MÉDICOS (EU) 2017/745 DEL PARLAMENTO EUROPEO Y CONSEJO EUROPEO  
EUROPAPARLAMENTETS OCH RÅDETS FÖRORDNING (EU) 2017/745 OM MEDICINTEKNISKA PRODUKTER

**Fabricante:** LM-Instruments Oy  
**Tillverkare:** SRN: FI-MF-000006705  
Norrbyn rantatie 8  
21600 Parainen  
Finland  
Tel. +358 2 4546 400

Za to izjavo o skladnosti je izključno odgovorno podjetje LM-Instruments Oy. S tem izjavljamo, da so izdelki, navedeni v dodatku A, skladni z uredbo (EU) 2017/745 za medicinske pripomočke z uporabo harmoniziranih standardov EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 in EN ISO 15223-1:2021. Izdelki so razvrščeni kot medicinski pripomočki razreda I.

Esta declaración de conformidad se realiza bajo la responsabilidad exclusiva de LM-Instruments Oy. Por la presente declaramos que los productos enumerados en el apéndice A cumplen con las regulaciones (UE) 2017/745 sobre dispositivos médicos mediante la aplicación de los estándares armonizados EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 y EN ISO 15223-1:2021. Los productos están clasificados como dispositivos médicos de clase I.

Denna försäkran om överensstämmelse är helt under LM-Instruments Oys ansvar. Härmed deklarerar vi att produkter som listas i bilaga A överensstämmer med förordningarna (EU) 2017/745 för medicintekniska produkter genom tillämpning av harmoniserade standarder EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 17664-1:2021, EN ISO 10993-18:2020 och EN ISO 15223-1:2021. Produkterna klassificeras som medicintekniska produkter, klass I.

Parainen 10.10.2025

Timo Helenius



Managing Director  
LM-Instruments Oy

**Appendix A, Non-cutting restorative instruments**

10.10.2025 rev. 13

MDR Class I based on rule 5

Intended use: Dental hand instrument for restorative operations

Basic UDI 6438311RESTO102Y

| <b>Code / Catalogue number</b> | <b>Trade Name</b>                        |
|--------------------------------|------------------------------------------|
| 130-131ES                      | LM Build-up Trimmer                      |
| 130-131EST                     | LM Build-up Trimmer DTS                  |
| 130-131ESTU                    | LM Build-up Trimmer DTS U                |
| 130-131XSI                     | LM Build-up Trimmer                      |
| 132-133ES                      | Enamel Chisel 1.2 mm                     |
| 132-133EST                     | Enamel Chisel 1.2 mm DTS                 |
| 132-133ESTU                    | Enamel Chisel 1.2 mm DTS U               |
| 132-133XSI                     | Enamel Chisel 1.2 mm                     |
| 29H-30HES                      | Base Carrier, rigid                      |
| 29H-30HEST                     | Base Carrier, rigid DTS                  |
| 29H-30HESTU                    | Base Carrier, rigid DTS U                |
| 29H-30HSI                      | Base Carrier, rigid                      |
| 29H-30HXSI                     | Base Carrier, rigid                      |
| 30-34ES                        | Base carrier Cond.malleab.tip            |
| 30-34EST                       | Base carrier Cond.malleab.tip DTS        |
| 30-34ESTU                      | Base carrier Cond.malleab.tip DTS U      |
| 30-34SI                        | Base carrier Cond.malleab.tip            |
| 30-34XSI                       | Base carrier Cond.malleab.tip            |
| 307-308DDES                    | Arte Eccesso DD                          |
| 307-308DDEST                   | Arte Eccesso DD DTS                      |
| 307-308DDESTU                  | Arte Eccesso DD DTS U                    |
| 307-308ES                      | Arte Eccesso                             |
| 307-308EST                     | Arte Eccesso DTS                         |
| 307-308ESTU                    | Arte Eccesso DTS U                       |
| 307-308XSI                     | Arte Eccesso                             |
| 30H-34ES                       | Base carrier-Condenser,rigid             |
| 30H-34EST                      | Base carrier-Condenser,rigid DTS         |
| 30H-34ESTU                     | Base carrier-Condenser,rigid DTS U       |
| 30H-34SI                       | Base carrier-Condenser,rigid             |
| 30H-34XSI                      | Base carrier-Condenser,rigid             |
| 31-32DDES                      | Burnisher                                |
| 31-32DDEST                     | Burnisher DTS                            |
| 31-32DDESTU                    | Burnisher DTS U                          |
| 31-32ES                        | Burnisher                                |
| 31-32EST                       | Burnisher DTS                            |
| 31-32ESTU                      | Burnisher DTS U                          |
| 31-32SI                        | Burnisher                                |
| 31-32XSI                       | Burnisher                                |
| 335-340DDES                    | Plugger 0.7-1.0 mm, cylindrical DD       |
| 335-340DDEST                   | Plugger 0.7-1.0 mm, cylindrical DD DTS   |
| 335-340DDESTU                  | Plugger 0.7-1.0 mm, cylindrical DD DTS U |
| 340-360ES                      | Plugger cylindrical 1.0-1.5mm            |
| 340-360EST                     | Plugger cylindrical 1.0-1.5mm DTS        |
| 340-360ESTU                    | Plugger cylindrical 1.0-1.5mm DTS U      |



|               |                                          |
|---------------|------------------------------------------|
| 340-360SI     | Plugger cylindrical 1.0-1.5mm            |
| 340-360XSI    | Plugger cylindrical 1.0-1.5mm            |
| 350-380ES     | Plugger cylindrical 1.2-2.0mm            |
| 350-380EST    | Plugger cylindrical 1.2-2.0mm DTS        |
| 350-380ESTU   | Plugger cylindrical 1.2-2.0mm DTS U      |
| 350-380PDLM   | Plugger, cylindrical 1.2-2.0mm Orbis     |
| 350-380PDOLM  | Plugger, cylindrical 1.2-2.0mm Orbis     |
| 350-380SI     | Plugger cylindrical 1.2-2.0mm            |
| 350-380XSI    | Plugger cylindrical 1.2-2.0mm            |
| 352-353DDES   | LM Build-up Shaper DD                    |
| 352-353DDEST  | LM Build-up Shaper DD DTS                |
| 352-353DDESTU | LM Build-up Shaper DD DTS U              |
| 370-390ES     | Plugger cylindrical 1.8-2.5mm            |
| 370-390EST    | Plugger cylindrical 1.8-2.5mm DTS        |
| 370-390ESTU   | Plugger cylindrical 1.8-2.5mm DTS U      |
| 370-390SI     | Plugger cylindrical 1.8-2.5mm            |
| 370-390XSI    | Plugger cylindrical 1.8-2.5mm            |
| 431-433DDES   | Arte Solo Anterior DD                    |
| 431-433DDEST  | Arte Solo Anterior DD DTS                |
| 431-433DDESTU | Arte Solo Anterior DD DTS U              |
| 431-433ES     | Arte Solo Anterior                       |
| 431-433EST    | Arte Solo Anterior DTS                   |
| 431-433XSI    | Arte Solo Anterior                       |
| 434-438DDES   | Arte Solo Posterior DD                   |
| 434-438DDEST  | Arte Solo Posterior DD DTS               |
| 434-438DDESTU | Arte Solo Posterior DD DTS U             |
| 434-438ES     | Arte Solo Posterior                      |
| 434-438EST    | Arte Solo Posterior DTS                  |
| 434-438XSI    | Arte Solo Posterior                      |
| 43-47DDES     | Plastic instrument, anterior             |
| 43-47DDEST    | Plastic instrument, anterior DTS         |
| 43-47DDESTU   | Plastic instrument, anterior DTS U       |
| 43-47ES       | Plastic instrument, anterior             |
| 43-47EST      | Plastic instrument, anterior DTS         |
| 43-47ESTU     | Plastic instrument, anterior DTS U       |
| 43-47PDLM     | Plastic Instrument, anterior Orbis       |
| 43-47PDOLM    | Plastic Instrument, anterior Orbis       |
| 43-47SI       | Plastic instrument, anterior             |
| 43-47XSI      | Plastic instrument, anterior             |
| 43-48XSI      | Plastic instrument, anterior - posterior |
| 442-443DDES   | Arte Modella DD                          |
| 442-443DDEST  | Arte Modella DD DTS                      |
| 442-443DDESTU | Arte Modella DD DTS U                    |
| 442-443ES     | Arte Modella                             |
| 442-443EST    | Arte Modella DTS                         |
| 442-443ESTU   | Arte Modella DTS U                       |
| 442-443XSI    | Arte Modella                             |
| 444-445DDES   | Mini Spatula                             |
| 444-445DDEST  | Mini Spatula DTS                         |
| 444-445DDESTU | Mini Spatula DTS U                       |

|               |                                            |
|---------------|--------------------------------------------|
| 444-445ES     | Mini Spatula                               |
| 444-445EST    | Mini Spatula DTS                           |
| 444-445ESTU   | Mini Spatula DTS U                         |
| 444-445PDOLM  | Mini Spatula Orbis                         |
| 444-445SI     | Mini Spatula                               |
| 444-445XSI    | Mini Spatula                               |
| 445-360XSI    | Mini Spatula - Plugger, cylindrical, 1.5mm |
| 445-473XSI    | Mini Spatula - Plugger, ball-ended, 2.5 mm |
| 445-483XSI    | Mini Spatula - Packer Modeller IO          |
| 445-702XSI    | Mini Spatula - Packer-Modeller IO p        |
| 446-447ES     | Composite Spatula 6                        |
| 446-447EST    | Composite Spatula 6 DTS                    |
| 446-447ESTU   | Composite Spatula 6 DTS U                  |
| 446-447PDLM   | Composite Spatula 6 Orbis                  |
| 446-447SI     | Composite Spatula 6                        |
| 446-447XSI    | Composite Spatula 6                        |
| 448-449DDES   | Arte Replica Posterior DD                  |
| 448-449DDEST  | Arte Replica Posterior DD DTS              |
| 448-449DDESTU | Arte Replica Posterior DD DTS U            |
| 448-449ES     | Arte Replica Posterior                     |
| 448-449EST    | Arte Replica Posterior DTS                 |
| 448-449ESTU   | Arte Replica Posterior DTS U               |
| 448-449XSI    | Arte Replica Posterior                     |
| 450-460ES     | Spatula                                    |
| 450-460EST    | Spatula DTS                                |
| 450-460ESTU   | Spatula DTS U                              |
| 450-460SI     | Spatula                                    |
| 450-460XSI    | Spatula                                    |
| 451-452DDES   | Arte Replica Anterior DD                   |
| 451-452DDEST  | Arte Replica Anterior DD DTS               |
| 451-452DDESTU | Arte Replica Anterior DD DTS U             |
| 451-452ES     | Arte Replica Anterior                      |
| 451-452EST    | Arte Replica Anterior DTS                  |
| 451-452ESTU   | Arte Replica Anterior DTS U                |
| 451-452XSI    | Arte Replica Anterior                      |
| 455-456XSI    | StickSTEPPER                               |
| 457-458XSI    | StickCARRIER                               |
| 464-494DDES   | Arte Applica Twist DD                      |
| 464-494DDEST  | Arte Applica Twist DD DTS                  |
| 464-494DDESTU | Arte Applica Twist DD DTS U                |
| 464-494ES     | Arte Applica Twist                         |
| 464-494EST    | Arte Applica Twist DTS                     |
| 464-494ESTU   | Arte Applica Twist DTS U                   |
| 464-494XSI    | Arte Applica Twist                         |
| 46-49DDES     | Arte Applica DD                            |
| 46-49DDEST    | Arte Applica DD DTS                        |
| 46-49DDESTU   | Arte Applica DD DTS U                      |
| 46-49ES       | Arte Applica                               |
| 46-49EST      | Arte Applica DTS                           |
| 46-49ESTU     | Arte Applica DTS U                         |



|               |                                               |
|---------------|-----------------------------------------------|
| 46-49XSI      | Arte Applica                                  |
| 468-469ES     | Arte Cusp Misura                              |
| 468-469EST    | Arte Cusp Misura DTS                          |
| 468-469XSI    | Arte Cusp Misura                              |
| 470-480ES     | Teflon Packer 1.2 mm                          |
| 470-480EST    | Teflon Packer 1.2 mm DTS                      |
| 470-480ESTU   | Teflon Packer 1.2 mm DTS U                    |
| 470-480XSI    | Teflon Packer 1.2 mm                          |
| 471-472XSI    | Burnisher - Plugger, ball-ended, 1.5-2.0 mm   |
| 471-473DDES   | Burnisher-Plugger 1.5-2.5mm ball-ended        |
| 471-473DDEST  | Burnisher-Plugger 1.5-2.5mm ball-ended DTS    |
| 471-473DDESTU | Burnisher-Plugger 1.5-2.5mm ball-ended DTS U  |
| 471-473ES     | Burnisher-Plugger 1.5-2.5mm ball-ended        |
| 471-473EST    | Burnisher-Plugger 1.5-2.5mm ball-ended DTS    |
| 471-473ESTU   | Burnisher-Plugger 1.5-2.5mm ball-ended DTS U  |
| 471-473PDLM   | Burnisher-plugger, ball-ended 1.5-2.5mm Orbis |
| 471-473PDOLM  | Burnisher-plugger, ball-ended 1.5-2.5mm Orbis |
| 471-473SI     | Burnisher-Plugger 1.5-2.5mm ball-ended        |
| 471-473XSI    | Burnisher-Plugger 1.5-2.5mm, ball-ended       |
| 476-477ES     | Burnisher 27-29                               |
| 476-477EST    | Burnisher 27-29 DTS                           |
| 476-477ESTU   | Burnisher 27-29 DTS U                         |
| 476-477SI     | Burnisher 27-29                               |
| 476-477XSI    | Burnisher 27-29                               |
| 481-487DDES   | Arte Fissura DD                               |
| 481-487DDEST  | Arte Fissura DD DTS                           |
| 481-487DDESTU | Arte Fissura DD DTS U                         |
| 481-487ES     | Arte Fissura                                  |
| 481-487EST    | Arte Fissura DTS                              |
| 481-487ESTU   | Arte Fissura DTS U                            |
| 481-487XSI    | Arte Fissura                                  |
| 482-483DDES   | Packer-Modeller IO                            |
| 482-483DDEST  | Packer-Modeller IO DTS                        |
| 482-483DDESTU | Packer-Modeller IO DTS U                      |
| 482-483ES     | Packer-Modeller IO                            |
| 482-483EST    | Packer-Modeller IO DTS                        |
| 482-483ESTU   | Packer-Modeller IO DTS U                      |
| 482-483SI     | Packer-Modeller IO                            |
| 482-483XSI    | Packer-Modeller IO                            |
| 482-702ES     | Packer-Modeller IO                            |
| 482-702EST    | Packer-Modeller IO DTS                        |
| 482-702ESTU   | Packer-Modeller IO DTS U                      |
| 482-702SI     | Packer-Modeller IO                            |
| 482-702XSI    | Packer-Modeller IO                            |
| 483-703ES     | Packer-Modeller IO                            |
| 483-703EST    | Packer-Modeller IO DTS                        |
| 483-703ESTU   | Packer-Modeller IO DTS U                      |
| 483-703SI     | Packer-Modeller IO                            |
| 483-703XSI    | Packer-Modeller IO                            |
| 484-485ES     | Flow Instrument IO                            |

|               |                                     |
|---------------|-------------------------------------|
| 484-485EST    | Flow Instrument IO DTS              |
| 484-485ESTU   | Flow Instrument IO DTS U            |
| 484-485XSI    | Flow Instrument IO                  |
| 485-707DDES   | LM Build-up Base DD                 |
| 485-707DDEST  | LM Build-up Base DD DTS             |
| 485-707DDESTU | LM Build-up Base DD DTS U           |
| 48-702DDES    | Plastic Instrument,posterior        |
| 48-702DDEST   | Plastic Instrument,posterior DTS    |
| 48-702DDESTU  | Plastic Instrument,posterior DTS U  |
| 48-702ES      | Plastic instrument, posterior       |
| 48-702EST     | Plastic instrument, posterior DTS   |
| 48-702ESTU    | Plastic instrument, posterior DTS U |
| 48-702PDLM    | Plastic Instrument, posterior Orbis |
| 48-702PDOLM   | Plastic Instrument, posterior Orbis |
| 48-702SI      | Plastic instrument, posterior       |
| 48-702XSI     | Plastic instrument, posterior       |
| 488-489DDES   | Arte Condensa DD                    |
| 488-489DDEST  | Arte Condensa DD DTS                |
| 488-489DDESTU | Arte Condensa DD DTS U              |
| 488-489ES     | Arte Condensa                       |
| 488-489EST    | Arte Condensa DTS                   |
| 488-489ESTU   | Arte Condensa DTS U                 |
| 488-489XSI    | Arte Condensa                       |
| 490-491ES     | Cord Packer 2.0mm                   |
| 490-491EST    | Cord Packer 2.0mm DTS               |
| 490-491ESTU   | Cord Packer 2.0mm DTS U             |
| 490-491SI     | Cord Packer 2.0mm                   |
| 490-491XSI    | Cord Packer 2.0mm                   |
| 492-493ES     | Cord Packer 2.6mm                   |
| 492-493EST    | Cord Packer 2.6mm DTS               |
| 492-493ESTU   | Cord Packer 2.6mm DTS U             |
| 492-493SI     | Cord Packer 2.6mm                   |
| 492-493XSI    | Cord Packer 2.6mm                   |
| 496-497DDES   | Arte Misura DD                      |
| 496-497DDEST  | Arte Misura DD DTS                  |
| 496-497DDESTU | Arte Misura DD DTS U                |
| 496-497ES     | Arte Misura                         |
| 496-497EST    | Arte Misura DTS                     |
| 496-497ESTU   | Arte Misura DTS U                   |
| 496-497XSI    | Arte Misura                         |
| 498-499DDES   | Arte Posterior Misura DD            |
| 498-499DDEST  | Arte Posterior Misura DD DTS        |
| 498-499DDESTU | Arte Posterior Misura DD DTS U      |
| 498-499ES     | Arte Posterior Misura               |
| 498-499EST    | Arte Posterior Misura DTS           |
| 498-499ESTU   | Arte Posterior Misura DTS U         |
| 498-499XSI    | Arte Posterior Misura               |
| 6657ES        | LM-CompoSet                         |
| 6657XSI       | LM-CompoSet                         |
| 6811ES        | LM Prepare and Build up Kit         |

|               |                                          |
|---------------|------------------------------------------|
| 6840ES        | ArteSet                                  |
| 6840XSI       | ArteSet                                  |
| 6844ES        | Arte Posterior Set                       |
| 6844XSI       | Arte Posterior Set                       |
| 6845ES        | LM-Arte Dark Diamond Set                 |
| 6846ES        | LM-Arte Dark Diamond Set Plus            |
| 6848ES        | Arte Complete Set                        |
| 6848XSI       | Arte Complete Set                        |
| 702-703ES     | Form Condenser 1.5-2.5mm                 |
| 702-703EST    | Form Condenser 1.5-2.5mm DTS             |
| 702-703ESTU   | Form Condenser 1.5-2.5mm DTS U           |
| 702-703PDOLM  | Form Condenser 1.5-2.5mm Orbis           |
| 702-703SI     | Form Condenser 1.5-2.5mm                 |
| 702-703XSI    | Form Condenser 1.5-2.5mm                 |
| 707-708DDES   | Modeller MH Mini                         |
| 707-708DDEST  | Modeller MH Mini DTS                     |
| 707-708DDESTU | Modeller MH Mini DTS U                   |
| 707-708ES     | Modeller MH Mini                         |
| 707-708EST    | Modeller MH Mini DTS                     |
| 707-708ESTU   | Modeller MH Mini DTS U                   |
| 707-708XSI    | Modeller MH Mini                         |
| 708-709DDES   | Modeller MH                              |
| 708-709DDEST  | Modeller MH DTS                          |
| 708-709DDESTU | Modeller MH DTS U                        |
| 708-709ES     | Modeller MH                              |
| 708-709EST    | Modeller MH DTS                          |
| 708-709ESTU   | Modeller MH DTS U                        |
| 708-709XSI    | Modeller MH                              |
| 71-72ES       | Universal Carver occlusal-proximal       |
| 71-72EST      | Universal Carver occlusal-proximal DTS   |
| 71-72ESTU     | Universal Carver occlusal-proximal DTS U |
| 71-72SI       | Universal Carver occlusal-proximal       |
| 71-72XSI      | Universal Carver occlusal-proximal       |
| 71-73ES       | Maehlum                                  |
| 71-73EST      | Maehlum DTS                              |
| 71-73ESTU     | Maehlum DTS U                            |
| 71-73SI       | Maehlum                                  |
| 71-73XSI      | Maehlum                                  |
| 731-732ES     | Cleoid-Discoid                           |
| 731-732EST    | Cleoid-Discoid DTS                       |
| 731-732ESTU   | Cleoid-Discoid DTS U                     |
| 731-732SI     | Cleoid-Discoid                           |
| 731-732XSI    | Cleoid-Discoid                           |
| 741-751ES     | Hollenback 1/2                           |
| 741-751EST    | Hollenback 1/2 DTS                       |
| 741-751ESTU   | Hollenback 1/2 DTS U                     |
| 741-751SI     | Hollenback 1/2                           |
| 741-751XSI    | Hollenback 1/2                           |
| 74-481XSI     | Nyström I - Modeller                     |
| 74-75ES       | Nyström I                                |



|             |                                             |
|-------------|---------------------------------------------|
| 74-75EST    | Nyström I DTS                               |
| 74-75ESTU   | Nyström I DTS U                             |
| 74-75PDOLM  | Carver Nyström I Orbis                      |
| 74-75SI     | Nyström I                                   |
| 74-75XSI    | Nyström I                                   |
| 7500        | Gingival Retractors Assortment              |
| 7502        | Gingival Retractors S                       |
| 7504        | Gingival Retractors M                       |
| 7506        | Gingival Retractors XL                      |
| 750-756ES   | Multiholder PK I                            |
| 750-756EST  | Multiholder PK I DTS                        |
| 750-756ESTU | Multiholder PK I DTS U                      |
| 750-756SI   | Multiholder PK I                            |
| 750-756XSI  | Multiholder PK I                            |
| 752-754ES   | Multiholder PK II                           |
| 752-754EST  | Multiholder PK II DTS                       |
| 752-754ESTU | Multiholder PK II DTS U                     |
| 752-754SI   | Multiholder PK II                           |
| 752-754XSI  | Multiholder PK II                           |
| 752-756ES   | Multiholder PK III Gengiva                  |
| 752-756EST  | Multiholder PK III Gengiva DTS              |
| 752-756ESTU | Multiholder PK III Gengiva DTS U            |
| 752-756XSI  | Multiholder PK III Gengiva                  |
| 7555        | Intro assortment, working ends              |
| 7555KES     | LM-MultiHolder IntroKit                     |
| 7555KXSI    | LM-MultiHolder IntroKit                     |
| 7556KES     | LM-GengivaKit                               |
| 7556KXSI    | LM-GengivaKit                               |
| 7600        | Cervical Matrices Assortment                |
| 7602        | Cervical Matrices for incisors              |
| 7604        | Cervical Matrices for canines and premolars |
| 7606        | Cervical Matrices for small molars          |
| 7608        | Cervical Matrices for large molars          |
| 7620        | Contact Formers Assortment                  |
| 7622        | Contact Formers XS                          |
| 7624        | Contact Formers S                           |
| 7626        | Contact Formers M                           |
| 7628        | Contact Formers L                           |
| 764-766ES   | Filling Remover                             |
| 764-766EST  | Filling Remover DTS                         |
| 764-766ESTU | Filling Remover DTS U                       |
| 764-766SI   | Filling Remover                             |
| 764-766XSI  | Filling Remover                             |
| 767-768ES   | Crown Off                                   |
| 767-768EST  | Crown Off DTS                               |
| 767-768ESTU | Crown Off DTS U                             |
| 767-768XSI  | Crown Off                                   |
| 76-77ES     | Nyström III                                 |
| 76-77EST    | Nyström III DTS                             |
| 76-77ESTU   | Nyström III DTS U                           |

|                  |                                   |
|------------------|-----------------------------------|
| 76-77PDLM        | Carver Nyström III Orbis          |
| 76-77PDOLM       | Carver Nyström III Orbis          |
| 76-77SI          | Nyström III                       |
| 76-77XSI         | Nyström III                       |
| 784-794ES        | Excess Scaler Mini                |
| 784-794EST       | Excess Scaler Mini DTS            |
| 784-794ESTU      | Excess Scaler Mini DTS U          |
| 784-794SI        | Excess Scaler Mini                |
| 784-794XSI       | Excess Scaler Mini                |
| 785-795ES        | Excess Scaler                     |
| 785-795EST       | Excess Scaler DTS                 |
| 785-795ESTU      | Excess Scaler DTS U               |
| 785-795SI        | Excess Scaler                     |
| 785-795XSI       | Excess Scaler                     |
| S444-445ESTGREY  | Mini Spatula DTS                  |
| S482-483ESTGREY  | Packer-Modeller IO DTS            |
| S48-702ESTGREY   | Plastic instrument, posterior DTS |
| S48-702ESTORANGE | Plastic instrument, posterior DTS |
| S490-491ESTRED   | Cord packer 2,0mm DTS             |

## Appendix A, diagnostic instruments

MDR Class I based on rule 5

Intended use: Dental hand instrument for diagnostic operations

Basic UDI 6438311DIAGNO10QV

| Code / Catalogue number | Trade name                       |
|-------------------------|----------------------------------|
| 11-12ES                 | Explorer                         |
| 11-12EST                | Explorer DTS                     |
| 11-12ESTU               | Explorer DTS U                   |
| 11-12SI                 | Explorer                         |
| 11-12XSI                | Explorer                         |
| 11F-12FES               | Flexplorer                       |
| 11F-12FEST              | Flexplorer DTS                   |
| 11F-12FESTU             | Flexplorer DTS U                 |
| 11F-12FXSI              | Flexplorer                       |
| 17-23ES                 | Explorer                         |
| 17-23EST                | Explorer DTS                     |
| 17-23ESTU               | Explorer DTS U                   |
| 17-23SI                 | Explorer                         |
| 17-23XSI                | Explorer                         |
| 17C-23ES                | Explorer, centered               |
| 17C-23EST               | Explorer, centered DTS           |
| 17C-23SI                | Explorer, centered               |
| 17C-23XSI               | Explorer, centered               |
| 17CXSI                  | Explorer, centered, se           |
| 17ES                    | Explorer, se                     |
| 17EST                   | Explorer, se DTS                 |
| 18-19ES                 | Explorer, prosthetic             |
| 18-19EST                | Explorer, prosthetic DTS         |
| 18-19ESTU               | Explorer, prosthetic DTS U       |
| 18-19SI                 | Explorer, prosthetic             |
| 18-19XSI                | Explorer, prosthetic             |
| 20-21ES                 | Nabers Probe                     |
| 20-21EST                | Nabers Probe DTS                 |
| 20-21ESTU               | Nabers Probe DTS U               |
| 20-21SI                 | Nabers Probe                     |
| 20-21XSI                | Nabers Probe                     |
| 20B-21BES               | Furcation Probe                  |
| 20B-21BEST              | Furcation Probe DTS              |
| 20B-21BESTU             | Furcation Probe DTS U            |
| 20B-21BSI               | Furcation Probe                  |
| 20B-21BXSI              | Furcation Probe                  |
| 23-520BES               | Explorer-Periodontal probe       |
| 23-520BEST              | Explorer-Periodontal probe DTS   |
| 23-520BESTU             | Explorer-Periodontal probe DTS U |
| 23-520BSI               | Explorer-Periodontal probe       |
| 23-520BXSI              | Explorer-Periodontal probe       |
| 23-52BES                | Explorer-Periodontal probe       |
| 23-52BEST               | Explorer-Periodontal probe DTS   |



|             |                                      |
|-------------|--------------------------------------|
| 23-52BESTU  | Explorer-Periodontal probe DTS U     |
| 23-52BSI    | Explorer-Periodontal probe           |
| 23-52BXSI   | Explorer-Periodontal probe           |
| 23-530BES   | Explorer-Periodontal probe           |
| 23-530BEST  | Explorer-Periodontal probe DTS       |
| 23-530BESTU | Explorer-Periodontal probe DTS U     |
| 23-530BSI   | Explorer-Periodontal probe           |
| 23-530BXSI  | Explorer-Periodontal probe           |
| 23-54BESTU  | Explorer-North Carolina Probe, DTS U |
| 23-550BES   | Explorer-WHO Probe                   |
| 23-550BEST  | Explorer-WHO Probe DTS               |
| 23-550BSI   | Explorer-WHO Probe                   |
| 23-550BXSI  | Explorer-WHO Probe                   |
| 23ES        | Explorer, se                         |
| 23EST       | Explorer, se DTS                     |
| 23SI        | Explorer, se                         |
| 23XSI       | Explorer, se                         |
| 25-473ES    | Mirror handle JM                     |
| 25-473EST   | Mirror handle JM DTS                 |
| 25-473ESTU  | Mirror handle JM DTS U               |
| 25-473XSI   | Mirror handle JM                     |
| 25-26ES     | Mirror handle, ortho                 |
| 25-26EST    | Mirror handle, ortho DTS             |
| 25-26ESTU   | Mirror handle, ortho DTS U           |
| 25-26XSI    | Mirror handle, ortho                 |
| 25ESBLUE    | Mirror handle 25 ES blue             |
| 25ESBLUET   | Mirror handle 25 ES blue DTS         |
| 25ESGREY    | Mirror handle 25 ES grey             |
| 25ESGREYT   | Mirror handle 25 ES grey DTS         |
| 25ESGREYTU  | Mirror handle 25 ES grey DTS U       |
| 25ESIBLUE   | Mirror handle 25 Esi blue            |
| 25ESIGREY   | Mirror handle 25 Esi grey            |
| 25ESIRED    | Mirror handle 25 Esi red             |
| 25ESRED     | Mirror handle 25 ES red              |
| 25ESREDT    | Mirror handle 25 ES red DTS          |
| 25SIBLUE    | Mirror handle 25 si blue             |
| 25SIGREY    | Mirror handle 25 si grey             |
| 25SIRED     | Mirror handle 25 si red              |
| 25XSIBLUE   | Mirror handle 25 Xsi blue            |
| 25XSIGREY   | Mirror handle 25 Xsi grey            |
| 25XSIRED    | Mirror handle 25 Xsi red             |
| 28-26ES     | Mirror handle UNF4-48, Ortho         |
| 28-26EST    | Mirror handle UNF4-48, Ortho DTS     |
| 28-26ESTU   | Mirror handle UNF4-48, Ortho DTS U   |
| 28-26XSI    | Mirror handle UNF4-48, Ortho         |
| 28ESBLUE    | Mirror handle 28 ES blue UNF4-48     |
| 28ESBLUET   | Mirror handle 28 ES blue UNF4-48 DTS |
| 28ESGREY    | Mirror handle 28 ES grey UNF4-48     |
| 28ESGREYT   | Mirror handle 28 ES grey UNF4-48 DTS |
| 28ESIBLUE   | Mirror handle 28 Esi blue UNF4-48    |

|           |                                     |
|-----------|-------------------------------------|
| 28ESIGREY | Mirror handle 28 Esi grey UNF4-48   |
| 28ESIRED  | Mirror handle 28 Esi red UNF4-48    |
| 28ESRED   | Mirror handle 28 ES red UNF4-48     |
| 28ESREDT  | Mirror handle 28 ES red UNF4-48 DTS |
| 28XSIBLUE | Mirror handle 28 Xsi blue UNF4-48   |
| 28XSIGREY | Mirror handle 28 Xsi grey UNF4-48   |
| 28XSIRED  | Mirror handle 28 Xsi red UNF4-48    |
| 29ES      | Explorer, Holst, se                 |
| 29EST     | Explorer, Holst, se DTS             |
| 29ESTU    | Explorer, Holst, se DTS U           |
| 29SI      | Explorer, Holst, se                 |
| 29XSI     | Explorer, Holst, se                 |
| 3-6ES     | Explorer                            |
| 3-6EST    | Explorer DTS                        |
| 3-6ESTU   | Explorer DTS U                      |
| 3-6XSI    | Explorer                            |
| 51ES      | Williams Probe, se                  |
| 51EST     | Williams Probe, se DTS              |
| 51SI      | Williams Probe, se                  |
| 51XSI     | Williams Probe, se                  |
| 52OBES    | Periodontal probe, se               |
| 52OBEST   | Periodontal probe, se DTS           |
| 52OBESTU  | Periodontal probe, se DTS U         |
| 52OBSI    | Periodontal probe, se               |
| 52OBXSI   | Periodontal probe, se               |
| 52BES     | Periodontal probe, se               |
| 52BEST    | Periodontal probe, se DTS           |
| 52BESTU   | Periodontal probe, se DTS U         |
| 52BSI     | Periodontal probe, se               |
| 52BXSI    | Periodontal probe, se               |
| 53OBES    | Periodontal probe, se               |
| 53OBEST   | Periodontal probe, se DTS           |
| 53OBESTU  | Periodontal probe, se DTS U         |
| 53OBSI    | Periodontal probe, se               |
| 53OBXSI   | Periodontal probe, se               |
| 53BES     | Marquis 12 Probe, se                |
| 53BEST    | Marquis 12 Probe, se DTS            |
| 53BXSI    | Marquis 12 Probe, se                |
| 54BES     | North Carolina Probe, se            |
| 54BEST    | North Carolina Probe, se DTS        |
| 54BXSI    | North Carolina Probe, se            |
| 55OBES    | WHO Probe, se                       |
| 55OBEST   | WHO Probe, se DTS                   |
| 55OBESTU  | WHO Probe, se DTS U                 |
| 55OBSI    | WHO Probe, se                       |
| 55OBXSI   | WHO Probe, se                       |
| 5-8ES     | Explorer                            |
| 5-8EST    | Explorer DTS                        |
| 5-8ESTU   | Explorer DTS U                      |
| 5-8SI     | Explorer                            |

|                  |                                  |
|------------------|----------------------------------|
| 5-8XSI           | Explorer                         |
| 5-9ES            | Explorer                         |
| 5-9EST           | Explorer DTS                     |
| 5-9ESTU          | Explorer DTS U                   |
| 5-9SI            | Explorer                         |
| 5-9XSI           | Explorer                         |
| 6ES              | Explorer, se                     |
| 8ES              | Explorer, se                     |
| 8-520BES         | Explorer-Periodontal Probe       |
| 8-520BEST        | Explorer-Periodontal Probe DTS   |
| 8-520BESTU       | Explorer-Periodontal Probe DTS U |
| 8-520BSI         | Explorer-Periodontal Probe       |
| 8-520BXSI        | Explorer-Periodontal Probe       |
| 8-550BES         | Explorer-WHO Probe               |
| 8-550BEST        | Explorer-WHO Probe DTS           |
| 8-550BSI         | Explorer-WHO Probe               |
| 8-550BXSI        | Explorer-WHO Probe               |
| 9-17CES          | Explorer, centered               |
| 9-17CEST         | Explorer, centered DTS           |
| 9-17CESTU        | Explorer, centered DTS U         |
| 9-17CXSI         | Explorer, centered               |
| 9ES              | Explorer, se                     |
| 9EST             | Explorer, se DTS                 |
| 9SI              | Explorer, se                     |
| 9XSI             | Explorer, se                     |
| S25ESTYELLOW     | Mirror handle, yellow DTS        |
| S25ESTORANGE     | Mirror handle, orange DTS        |
| S25ESTGREEN      | Mirror handle, green DTS         |
| S17C-23ESTYELLOW | Explorer DTS                     |
| S17C-23ESTBLUE   | Explorer DTS                     |
| S17C-23ESTGREEN  | Explorer DTS                     |
| S17C-23ESTRED    | Explorer DTS                     |
| S51ESTBLUE       | Williams probe DTS               |
| S51ESTYELLOW     | Williams probe DTS               |
| S51ESTGREY       | Williams probe DTS               |
| S51ESTGREEN      | Williams probe DTS               |
| S51ESTRED        | Williams probe DTS               |
| 9-23XSI          | Explorer 9-23                    |
| 25PDOLM          | Mirror handle 25 (blue) Orbis    |
| 5-8PDOLM         | Explorer Orbis                   |
| 29PDOLM          | Explorer, Holst, se Orbis        |
| 18-19PDOLM       | Explorer, prosthetic Orbis       |
| 23-520BPDOLM     | Explorer-Periodontal probe Orbis |
| 550BPDOLM        | WHO Probe, se Orbis              |
| 5-9PDLM          | Explorer Orbis                   |
| 17-23PDLM        | Explorer Orbis                   |
| 17C-23ESTU       | Explorer, centered DTS U         |
| 17CSI            | Explorer, centered, se           |
| 17ESTU           | Explorer, se DTS U               |
| 17XSI            | Explorer, se                     |

|              |                                         |
|--------------|-----------------------------------------|
| 23-51ES      | Explorer-Williams Probe                 |
| 23-51EST     | Explorer-Williams Probe DTS             |
| 23-51XSI     | Explorer-Williams Probe                 |
| 23-54BES     | Explorer - North Carolina Probe 54B     |
| 23-550BESTU  | Explorer-WHO Probe DTS U                |
| 23ESTU       | Explorer, se DTS U                      |
| 25ESBLUETU   | Mirror handle 25 ES blue DTS U          |
| 25ESREDTU    | Mirror handle 25 ES red DTS U           |
| 25PDLM       | Mirror handle 25 Orbis                  |
| 28ESBLUETU   | Mirror handle 28 ES blue UNF4-48 DTS U  |
| 28ESGREYTU   | Mirror handle 28 ES grey UNF4-48 DTS U  |
| 28ESREDTU    | Mirror handle 28 ES red UNF4-48 DTS U   |
| 3-6SI        | Explorer                                |
| 51ESTU       | Williams Probe, se DTS U                |
| 53BESTU      | Marquis 12 Probe, se DTS U              |
| 54BESTU      | North Carolina Probe, se DTS U          |
| 5SI          | Explorer, se                            |
| 5XSI         | Explorer, se                            |
| 6XSI         | Explorer, se                            |
| 8-550BESTU   | Explorer-WHO Probe DTS U                |
| 8EST         | Explorer, se DTS                        |
| 8ESTU        | Explorer, se DTS U                      |
| 8XSI         | Explorer, se                            |
| 9-17CSI      | Explorer, centered                      |
| 99911F12FES  | Flexplorer ErgoSense (With Compliments) |
| 99911F12FXSI | Flexplorer ErgoMax (With Compliments)   |
| 9ESTU        | Explorer, se DTS U                      |



**Appendix A, endodontic instruments**

MDR Class I based on rule 5

Intended use: Dental hand instrument for endodontic operations

Basic UDI 6438311ENDO10PV

| <b>Code / Catalogue number</b> | <b>Trade Name</b>                           |
|--------------------------------|---------------------------------------------|
| 41-42ES                        | Endo Plugger 0.5-1.0mm                      |
| 41-42EST                       | Endo Plugger 0.5-1.0mm DTS                  |
| 41-42SI                        | Endo Plugger 0.5-1.0mm                      |
| 41-42XSI                       | Endo Plugger 0.5-1.0mm                      |
| 22-24ESTU                      | Endo Spreader DTS U DE special 0,23 / 0,4mm |
| 22ES                           | Endo Spreader 0,23mm                        |
| 22EST                          | Endo Spreader 0,23mm DTS                    |
| 22XSI                          | Endo Spreader 0,23mm                        |
| 24ES                           | Endo Spreader 0,4mm                         |
| 24EST                          | Endo Spreader 0,4mm DTS                     |
| 24ESTU                         | Endo Spreader 0,4mm DTS U                   |
| 24XSI                          | Endo Spreader 0,4mm                         |
| S41-42ESTORANGE                | Endo plugger 0,5-1,0 mm DTS                 |
| 41-42ESTU                      | Endo Plugger 0.5-1.0mm DTS U                |
| 22ESTU                         | Endo Spreader 0,23mm DTS U                  |
| 27-28ES                        | Root Canal Explorer                         |
| 27-28SI                        | Root Canal Explorer                         |
| 27-28XSI                       | Root Canal Explorer                         |
| 27-28EST                       | Root Canal Explorer DTS                     |
| S27-28ESTORANGE                | Root canal explorer DTS                     |
| 27-28ESTU                      | Root Canal Explorer DTS U                   |

**Appendix A, orthodontic instruments**

MDR Class I based on rule 5

Intended use: Dental hand instrument for orthodontic operations

Basic UDI 6438311ORTHO104D

| <b>Code / Catalogue number</b> | <b>Trade Name</b>                 |
|--------------------------------|-----------------------------------|
| 411-415ES                      | Ligature Director                 |
| 411-415EST                     | Ligature Director DTS             |
| 411-415ESTU                    | Ligature Director DTS U           |
| 411-415XSI                     | Ligature Director                 |
| 412-413ES                      | Arch Wire Tucker                  |
| 412-413EST                     | Arch Wire Tucker DTS              |
| 412-413ESTU                    | Arch Wire Tucker DTS U            |
| 412-413XSI                     | Arch Wire Tucker                  |
| 414-150ES                      | Ligature Tucker-Scaler U15        |
| 414-150EST                     | Ligature Tucker-Scaler U15 DTS    |
| 414-150SI                      | Ligature Tucker-Scaler U15        |
| 414-150XSI                     | Ligature Tucker-Scaler U15        |
| 414-17CLES                     | Ligature On Off SL                |
| 414-17CLEST                    | Ligature On Off SL DTS            |
| 414-17CLESTU                   | Ligature On Off SL DTS U          |
| 414-17CLXSI                    | Ligature On Off SL                |
| 414-415ES                      | Ligature Tucker                   |
| 414-415EST                     | Ligature Tucker DTS               |
| 414-415ESTU                    | Ligature Tucker DTS U             |
| 414-415SI                      | Ligature Tucker                   |
| 414-415XSI                     | Ligature Tucker                   |
| 416-417ES                      | Plastic Ligature Applicator       |
| 416-417EST                     | Plastic Ligature Applicator DTS   |
| 416-417ESTU                    | Plastic Ligature Applicator DTS U |
| 416-417SI                      | Plastic Ligature Applicator       |
| 416-417XSI                     | Plastic Ligature Applicator       |
| 414-150ESTU                    | Ligature Tucker-Scaler U15 DTS U  |
| 423XSI                         | RMO Ligature Remover              |
| 436-437XSI                     | RMO Liberty Bielle Instrument     |

## Appendix A, removable orthodontic appliances

MDR Class I based on rule 5

Intended use: Removable orthodontic appliance

Basic UDI 6438311ROA10UU

| Code / Catalogue number | Trade name                         |
|-------------------------|------------------------------------|
| 94020HS                 | LM-Activator 20HIGH (short)        |
| 94020LS                 | LM-Activator 20LOW (short)         |
| 94025HS                 | LM-Activator 25HIGH (short)        |
| 94025LS                 | LM-Activator 25LOW (short)         |
| 94030HS                 | LM-Activator 30HIGH (short)        |
| 94030LS                 | LM-Activator 30LOW (short)         |
| 94035HS                 | LM-Activator 35HIGH (short)        |
| 94035LS                 | LM-Activator 35LOW (short)         |
| 94040HS                 | LM-Activator 40HIGH (short)        |
| 94040L                  | LM-Activator 40LOW                 |
| 94040LS                 | LM-Activator 40LOW (short)         |
| 94045H                  | LM-Activator 45HIGH                |
| 94045HS                 | LM-Activator 45HIGH (short)        |
| 94045L                  | LM-Activator 45LOW                 |
| 94045LR                 | LM-Activator 45LOW Reinforced      |
| 94045LS                 | LM-Activator 45LOW (short)         |
| 94050H                  | LM-Activator 50HIGH                |
| 94050HS                 | LM-Activator 50HIGH (short)        |
| 94050L                  | LM-Activator 50LOW                 |
| 94050LR                 | LM-Activator 50LOW Reinforced      |
| 94050LS                 | LM-Activator 50LOW (short)         |
| 94055H                  | LM-Activator 55HIGH                |
| 94055HS                 | LM-Activator 55HIGH (short)        |
| 94055L                  | LM-Activator 55LOW                 |
| 94055LR                 | LM-Activator 55LOW Reinforced      |
| 94055LS                 | LM-Activator 55LOW (short)         |
| 94060H                  | LM-Activator 60HIGH                |
| 94060HS                 | LM-Activator 60HIGH (short)        |
| 94060L                  | LM-Activator 60LOW                 |
| 94060LR                 | LM-Activator 60LOW Reinforced      |
| 94060LS                 | LM-Activator 60LOW (short)         |
| 94065H                  | LM-Activator 65HIGH                |
| 94065HS                 | LM-Activator 65HIGH (short)        |
| 94065L                  | LM-Activator 65LOW                 |
| 94065LS                 | LM-Activator 65LOW (short)         |
| 94070H                  | LM-Activator 70HIGH                |
| 94070HS                 | LM-Activator 70HIGH (short)        |
| 94070L                  | LM-Activator 70LOW                 |
| 94070LS                 | LM-Activator 70LOW (short)         |
| 94235HLN                | LM-Activator2 High Long 35 Narrow  |
| 94235HLW                | LM-Activator2 High Long 35 Wide    |
| 94235HSN                | LM-Activator2 High Short 35 Narrow |
| 94235HSW                | LM-Activator2 High Short 35 Wide   |
| 94235LLN                | LM-Activator2 Low Long 35 Narrow   |

|           |                                              |
|-----------|----------------------------------------------|
| 94235LLNR | LM-Activator2 Low Long 35 Narrow Reinforced  |
| 94235LLW  | LM-Activator2 Low Long 35 Wide               |
| 94235LLWR | LM-Activator2 Low Long 35 Wide Reinforced    |
| 94235LSN  | LM-Activator2 Low Short 35 Narrow            |
| 94235LSNR | LM-Activator2 Low Short 35 Narrow Reinforced |
| 94235LSW  | LM-Activator2 Low Short 35 Wide              |
| 94235LSWR | LM-Activator2 Low Short 35 Wide Reinforced   |
| 94240HLN  | LM-Activator2 High Long 40 Narrow            |
| 94240HLW  | LM-Activator2 High Long 40 Wide              |
| 94240HSN  | LM-Activator2 High Short 40 Narrow           |
| 94240HSW  | LM-Activator2 High Short 40 Wide             |
| 94240LLN  | LM-Activator2 Low Long 40 Narrow             |
| 94240LLNR | LM-Activator2 Low Long 40 Narrow Reinforced  |
| 94240LLW  | LM-Activator2 Low Long 40 Wide               |
| 94240LLWR | LM-Activator2 Low Long 40 Wide Reinforced    |
| 94240LSN  | LM-Activator2 Low Short 40 Narrow            |
| 94240LSNR | LM-Activator2 Low Short 40 Narrow Reinforced |
| 94240LSW  | LM-Activator2 Low Short 40 Wide              |
| 94240LSWR | LM-Activator2 Low Short 40 Wide Reinforced   |
| 94245HLN  | LM-Activator2 High Long 45 Narrow            |
| 94245HLW  | LM-Activator2 High Long 45 Wide              |
| 94245HSN  | LM-Activator2 High Short 45 Narrow           |
| 94245HSW  | LM-Activator2 High Short 45 Wide             |
| 94245LLN  | LM-Activator2 Low Long 45 Narrow             |
| 94245LLNR | LM-Activator2 Low Long 45 Narrow Reinforced  |
| 94245LLW  | LM-Activator2 Low Long 45 Wide               |
| 94245LLWR | LM-Activator2 Low Long 45 Wide Reinforced    |
| 94245LSN  | LM-Activator2 Low Short 45 Narrow            |
| 94245LSNR | LM-Activator2 Low Short 45 Narrow Reinforced |
| 94245LSW  | LM-Activator2 Low Short 45 Wide              |
| 94245LSWR | LM-Activator2 Low Short 45 Wide Reinforced   |
| 94250HLN  | LM-Activator2 High Long 50 Narrow            |
| 94250HLW  | LM-Activator2 High Long 50 Wide              |
| 94250HSN  | LM-Activator2 High Short 50 Narrow           |
| 94250HSW  | LM-Activator2 High Short 50 Wide             |
| 94250LLN  | LM-Activator2 Low Long 50 Narrow             |
| 94250LLNR | LM-Activator2 Low Long 50 Narrow Reinforced  |
| 94250LLW  | LM-Activator2 Low Long 50 Wide               |
| 94250LLWR | LM-Activator2 Low Long 50 Wide Reinforced    |
| 94250LSN  | LM-Activator2 Low Short 50 Narrow            |
| 94250LSNR | LM-Activator2 Low Short 50 Narrow Reinforced |
| 94250LSW  | LM-Activator2 Low Short 50 Wide              |
| 94250LSWR | LM-Activator2 Low Short 50 Wide Reinforced   |
| 94255HLN  | LM-Activator2 High Long 55 Narrow            |
| 94255HLW  | LM-Activator2 High Long 55 Wide              |
| 94255HSN  | LM-Activator2 High Short 55 Narrow           |
| 94255HSW  | LM-Activator2 High Short 55 Wide             |
| 94255LLN  | LM-Activator2 Low Long 55 Narrow             |
| 94255LLNR | LM-Activator2 Low Long 55 Narrow Reinforced  |
| 94255LLW  | LM-Activator2 Low Long 55 Wide               |

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|-----------|----------------------------------------------|
| 94255LLWR | LM-Activator2 Low Long 55 Wide Reinforced    |
| 94255LSN  | LM-Activator2 Low Short 55 Narrow            |
| 94255LSNR | LM-Activator2 Low Short 55 Narrow Reinforced |
| 94255LSW  | LM-Activator2 Low Short 55 Wide              |
| 94255LSWR | LM-Activator2 Low Short 55 Wide Reinforced   |
| 94260HLN  | LM-Activator2 High Long 60 Narrow            |
| 94260HLW  | LM-Activator2 High Long 60 Wide              |
| 94260HSN  | LM-Activator2 High Short 60 Narrow           |
| 94260HSW  | LM-Activator2 High Short 60 Wide             |
| 94260LLN  | LM-Activator2 Low Long 60 Narrow             |
| 94260LLNR | LM-Activator2 Low Long 60 Narrow Reinforced  |
| 94260LLW  | LM-Activator2 Low Long 60 Wide               |
| 94260LLWR | LM-Activator2 Low Long 60 Wide Reinforced    |
| 94260LSN  | LM-Activator2 Low Short 60 Narrow            |
| 94260LSNR | LM-Activator2 Low Short 60 Narrow Reinforced |
| 94260LSW  | LM-Activator2 Low Short 60 Wide              |
| 94260LSWR | LM-Activator2 Low Short 60 Wide Reinforced   |
| 94265HLN  | LM-Activator2 High Long 65 Narrow            |
| 94265HLW  | LM-Activator2 High Long 65 Wide              |
| 94265HSN  | LM-Activator2 High Short 65 Narrow           |
| 94265HSW  | LM-Activator2 High Short 65 Wide             |
| 94265LLN  | LM-Activator2 Low Long 65 Narrow             |
| 94265LLNR | LM-Activator2 Low Long 65 Narrow Reinforced  |
| 94265LLW  | LM-Activator2 Low Long 65 Wide               |
| 94265LLWR | LM-Activator2 Low Long 65 Wide Reinforced    |
| 94265LSN  | LM-Activator2 Low Short 65 Narrow            |
| 94265LSNR | LM-Activator2 Low Short 65 Narrow Reinforced |
| 94265LSW  | LM-Activator2 Low Short 65 Wide              |
| 94265LSWR | LM-Activator2 Low Short 65 Wide Reinforced   |
| 94270HLN  | LM-Activator2 High Long 70 Narrow            |
| 94270HLW  | LM-Activator2 High Long 70 Wide              |
| 94270HSN  | LM-Activator2 High Short 70 Narrow           |
| 94270HSW  | LM-Activator2 High Short 70 Wide             |
| 94270LLN  | LM-Activator2 Low Long 70 Narrow             |
| 94270LLNR | LM-Activator2 Low Long 70 Narrow Reinforced  |
| 94270LLW  | LM-Activator2 Low Long 70 Wide               |
| 94270LLWR | LM-Activator2 Low Long 70 Wide Reinforced    |
| 94270LSN  | LM-Activator2 Low Short 70 Narrow            |
| 94270LSNR | LM-Activator2 Low Short 70 Narrow Reinforced |
| 94270LSW  | LM-Activator2 Low Short 70 Wide              |
| 94270LSWR | LM-Activator2 Low Short 70 Wide Reinforced   |
| 943104113 | LM-Dental 104113                             |
| 943104243 | LM-Dental 104243                             |
| 943105313 | LM-Dental 105313                             |
| 943112345 | LM-Dental 112345                             |
| 943112346 | LM-Dental 112346                             |
| 943112347 | LM-Dental 112347                             |
| 943112348 | LM-Dental 112348                             |
| 943117383 | LM-Dental 117383                             |
| 943120450 | LM-Dental 120450                             |



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| 943120454 | LM-Dental 120454 |
| 943121253 | LM-Dental 121253 |
| 943125773 | LM-Dental 125773 |
| 943133414 | LM-Dental 133414 |
| 943134329 | LM-Dental 134329 |
| 943134963 | LM-Dental 134963 |
| 943140348 | LM-Dental 140348 |
| 943142839 | LM-Dental 142839 |
| 943144341 | LM-Dental 144341 |
| 943145713 | LM-Dental 145713 |
| 943146723 | LM-Dental 146723 |
| 943147509 | LM-Dental 147509 |
| 943156348 | LM-Dental 156348 |
| 943158733 | LM-Dental 158733 |
| 943165414 | LM-Dental 165414 |
| 943171255 | LM-Dental 171255 |
| 943173261 | LM-Dental 173261 |
| 943177330 | LM-Dental 177330 |
| 943184236 | LM-Dental 184236 |
| 943197336 | LM-Dental 197336 |
| 943197490 | LM-Dental 197490 |
| 943201041 | LM-Dental 201041 |
| 943205104 | LM-Dental 205104 |
| 943209329 | LM-Dental 209329 |
| 943210047 | LM-Dental 210047 |
| 943223656 | LM-Dental 223656 |
| 943241060 | LM-Dental 241060 |
| 943245831 | LM-Dental 245831 |
| 943248472 | LM-Dental 248472 |
| 943254036 | LM-Dental 254036 |
| 943254567 | LM-Dental 254567 |
| 943255803 | LM-Dental 255803 |
| 943261449 | LM-Dental 261449 |
| 943264262 | LM-Dental 264262 |
| 943269167 | LM-Dental 269167 |
| 943269439 | LM-Dental 269439 |
| 943276706 | LM-Dental 276706 |
| 943281586 | LM-Dental 281586 |
| 943285365 | LM-Dental 285365 |
| 943290336 | LM-Dental 290336 |
| 943297148 | LM-Dental 297148 |
| 943304959 | LM-Dental 304959 |
| 943306497 | LM-Dental 306497 |
| 943317768 | LM-Dental 317768 |
| 943325831 | LM-Dental 325831 |
| 943327325 | LM-Dental 327325 |
| 943330300 | LM-Dental 330300 |
| 943333269 | LM-Dental 333269 |
| 943336918 | LM-Dental 336918 |
| 943343469 | LM-Dental 343469 |

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| 943344442 | LM-Dental 344442 |
| 943350558 | LM-Dental 350558 |
| 943354496 | LM-Dental 354496 |
| 943357691 | LM-Dental 357691 |
| 943358549 | LM-Dental 358549 |
| 943372865 | LM-Dental 372865 |
| 943381904 | LM-Dental 381904 |
| 943398074 | LM-Dental 398074 |
| 943398864 | LM-Dental 398864 |
| 943406612 | LM-Dental 406612 |
| 943411346 | LM-Dental 411346 |
| 943415036 | LM-Dental 415036 |
| 943415929 | LM-Dental 415929 |
| 943425589 | LM-Dental 425589 |
| 943434342 | LM-Dental 434342 |
| 943435342 | LM-Dental 435342 |
| 943435545 | LM-Dental 435545 |
| 943435741 | LM-Dental 435741 |
| 943440683 | LM-Dental 440683 |
| 943450118 | LM-Dental 450118 |
| 943452283 | LM-Dental 452283 |
| 943452916 | LM-Dental 452916 |
| 943466663 | LM-Dental 466663 |
| 943471683 | LM-Dental 471683 |
| 943477744 | LM-Dental 477744 |
| 943479694 | LM-Dental 479694 |
| 943485177 | LM-Dental 485177 |
| 943498497 | LM-Dental 498497 |
| 943505379 | LM-Dental 505379 |
| 943507303 | LM-Dental 507303 |
| 943511622 | LM-Dental 511622 |
| 943522078 | LM-Dental 522078 |
| 943522636 | LM-Dental 522636 |
| 943526874 | LM-Dental 526874 |
| 943529121 | LM-Dental 529121 |
| 943530151 | LM-Dental 530151 |
| 943542986 | LM-Dental 542986 |
| 943551713 | LM-Dental 551713 |
| 943560371 | LM-Dental 560371 |
| 943560904 | LM-Dental 560904 |
| 943563487 | LM-Dental 563487 |
| 943574822 | LM-Dental 574822 |
| 943585628 | LM-Dental 585628 |
| 943594271 | LM-Dental 594271 |
| 943602823 | LM-Dental 602823 |
| 943609645 | LM-Dental 609645 |
| 943615192 | LM-Dental 615192 |
| 943625532 | LM-Dental 625532 |
| 943625811 | LM-Dental 625811 |
| 943627206 | LM-Dental 627206 |

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| 943632528 | LM-Dental 632528 |
| 943642876 | LM-Dental 642876 |
| 943644059 | LM-Dental 644059 |
| 943645005 | LM-Dental 645005 |
| 943647856 | LM-Dental 647856 |
| 943656119 | LM-Dental 656119 |
| 943658460 | LM-Dental 658460 |
| 943661396 | LM-Dental 661396 |
| 943663458 | LM-Dental 663458 |
| 943672755 | LM-Dental 672755 |
| 943722167 | LM-Dental 722167 |
| 943723231 | LM-Dental 723231 |
| 943728213 | LM-Dental 728213 |
| 943728826 | LM-Dental 728826 |
| 943739161 | LM-Dental 739161 |
| 943750690 | LM-Dental 750690 |
| 943765211 | LM-Dental 765211 |
| 943765906 | LM-Dental 765906 |
| 943768107 | LM-Dental 768107 |
| 943777071 | LM-Dental 777071 |
| 943783605 | LM-Dental 783605 |
| 943792149 | LM-Dental 792149 |
| 943806063 | LM-Dental 806063 |
| 943809387 | LM-Dental 809387 |
| 943811026 | LM-Dental 811026 |
| 943811199 | LM-Dental 811199 |
| 943823841 | LM-Dental 823841 |
| 943824425 | LM-Dental 824425 |
| 943831397 | LM-Dental 831397 |
| 943837794 | LM-Dental 837794 |
| 943839875 | LM-Dental 839875 |
| 943844924 | LM-Dental 844924 |
| 943845863 | LM-Dental 845863 |
| 943854111 | LM-Dental 854111 |
| 943860660 | LM-Dental 860660 |
| 943868604 | LM-Dental 868604 |
| 943870276 | LM-Dental 870276 |
| 943882948 | LM-Dental 882948 |
| 943887799 | LM-Dental 887799 |
| 943888970 | LM-Dental 888970 |
| 943898460 | LM-Dental 898460 |
| 943906664 | LM-Dental 906664 |
| 943911158 | LM-Dental 911158 |
| 943913842 | LM-Dental 913842 |
| 943914300 | LM-Dental 914300 |
| 943918624 | LM-Dental 918624 |
| 943920798 | LM-Dental 920798 |
| 943929217 | LM-Dental 929217 |
| 943932490 | LM-Dental 932490 |
| 943938179 | LM-Dental 938179 |

|           |                            |
|-----------|----------------------------|
| 943940837 | LM-Dental 940837           |
| 943944249 | LM-Dental 944249           |
| 943944683 | LM-Dental 944683           |
| 943951889 | LM-Dental 951889           |
| 943955490 | LM-Dental 955490           |
| 943961424 | LM-Dental 961424           |
| 943962045 | LM-Dental 962045           |
| 943975993 | LM-Dental 975993           |
| 943983092 | LM-Dental 983092           |
| 943994985 | LM-Dental 994985           |
| 943998453 | LM-Dental 998453           |
| 94100S    | LM-Trainer Small           |
| 94100T    | LM-Trainer Medium          |
| 94100T2   | LM-Trainer 2 Medium        |
| 94100TB   | LM-Trainer Braces          |
| 94025H    | LM-Dental 486073           |
| 94030H    | LM-Dental 915929           |
| 94035H    | LM-Dental 578318           |
| 94010L    | LM-Dental 283648           |
| 94015L    | LM-Dental 153768           |
| 94020L    | LM-Dental 661234           |
| 94030L    | LM-Dental 904931           |
| 94035L    | LM-Dental 618836           |
| 943286347 | LM-Dental 286347           |
| 94020H    | LM-Dental 591430           |
| 94040H    | LM-Dental 475167           |
| 94025L    | LM-Dental 794062           |
| 94010LS   | LM-Activator 10LOW (short) |
| 94015LS   | LM-Activator 15LOW (short) |
| 943140436 | LM-Dental 140436           |
| 943149262 | LM-Dental 149262           |
| 943153599 | LM-Dental 153599           |
| 943167040 | LM-Dental 167040           |
| 943186601 | LM-Dental 186601           |
| 943198655 | LM-Dental 198655           |
| 943217187 | LM-Dental 217187           |
| 943235790 | LM-Dental 235790           |
| 943251856 | LM-Dental 251856           |
| 943261088 | LM-Dental 261088           |
| 943274971 | LM-Dental 274971           |
| 943294659 | LM-Dental 294659           |
| 943297834 | LM-Dental 297834           |
| 943313926 | LM-Dental 313926           |
| 943391830 | LM-Dental 391830           |
| 943475071 | LM-Dental 475071           |
| 943503859 | LM-Dental 503859           |
| 943528759 | LM-Dental 528759           |
| 943644357 | LM-Dental 644357           |
| 943658599 | LM-Dental 658599           |
| 943673833 | LM-Dental 673833           |

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|-----------|-------------------------------|
| 943687914 | LM-Dental 687914              |
| 943724594 | LM-Dental 724594              |
| 943748453 | LM-Dental 748453              |
| 943752959 | LM-Dental 752959              |
| 943767972 | LM-Dental 767972              |
| 943781499 | LM-Dental 781499              |
| 943905136 | LM-Dental 905136              |
| 943905966 | LM-Dental 905966              |
| 943912149 | LM-Dental 912149              |
| 943944210 | LM-Dental 944210              |
| 943968918 | LM-Dental 968918              |
| 94435LS   | My LM-Activator 35 Low Short  |
| 94440HS   | My LM-Activator 40 High Short |
| 94440LL   | My LM-Activator 40 Low Long   |
| 94440LS   | My LM-Activator 40 Low Short  |
| 94445HL   | My LM-Activator 45 High Long  |
| 94445HS   | My LM-Activator 45 High Short |
| 94445LL   | My LM-Activator 45 Low Long   |
| 94445LS   | My LM-Activator 45 Low Short  |
| 94450HL   | My LM-Activator 50 High Long  |
| 94450HS   | My LM-Activator 50 High Short |
| 94450LL   | My LM-Activator 50 Low Long   |
| 94450LS   | My LM-Activator 50 Low Short  |
| 94455HL   | My LM-Activator 55 High Long  |
| 94455HS   | My LM-Activator 55 High Short |
| 94455LL   | My LM-Activator 55 Low Long   |
| 94455LS   | My LM-Activator 55 Low Short  |
| 94460HL   | My LM-Activator 60 High Long  |
| 94460HS   | My LM-Activator 60 High Short |
| 94460LL   | My LM-Activator 60 Low Long   |
| 94460LS   | My LM-Activator 60 Low Short  |
| 94465HS   | My LM-Activator 65 High Short |
| 94465LL   | My LM-Activator 65 Low Long   |
| 94465LS   | My LM-Activator 65 Low Short  |
| 94470LS   | My LM-Activator 70 Low Short  |

**Appendix A, LM-OrthoSizer2**

MDR Class I based on rule 5

LM-Orthosizer

Intended use: To aid in the selection of the appropriate size of a removable orthodontic device LM-Activator

Basic UDI 6438311ORTHOSIZER10GC

| <b>Code / Catalogue number</b> | <b>Trade name</b>         |
|--------------------------------|---------------------------|
| 9400                           | LM-OrthoSizer             |
| 9402                           | LM-Activator 2 OrthoSizer |



**Appendix A, instrument cassettes, trays and assessories**

MDR Class I based on rule 1

Intended use: Device for storing dental instruments and protecting the instruments and users

Basic UDI 6438311CASSETTES10KT

| <b>Code / Catalogue number</b> | <b>Trade name</b>                                       |
|--------------------------------|---------------------------------------------------------|
| 6410                           | ServoMax Tray Set, incl. 2 univ. trapper, 2 metal clips |
| 6420                           | ServoMax standard case                                  |
| 6430                           | ServoMax restauration / endo case                       |
| 6435                           | ServoMax foam, 20pcs                                    |
| 6450                           | ServoMax bur / endofile case                            |
| 6460                           | ServoMax ultrasonic tip case                            |
| 6471                           | ServoMax instrument rack,black (2pcs)                   |
| 6472                           | ServoMax instrument rack,orang (2pcs)                   |
| 6473                           | ServoMax instrument rack,blue (2pcs)                    |
| 6474                           | ServoMax instrument rack,red (2pcs)                     |
| 6475                           | ServoMax instrument rack,green (2pcs)                   |
| 6490                           | ServoMax cup holder                                     |
| 6495                           | ServoMax Syringe holder                                 |
| 6551                           | Servo 5E, grey                                          |
| 6552                           | Servo 5E, blue                                          |
| 6553                           | Servo 5E, green                                         |
| 6554                           | Servo 5E, yellow                                        |
| 6581                           | Servo 8E, grey                                          |
| 6582                           | Servo 8E, blue                                          |
| 6583                           | Servo 8E, green                                         |
| 6584                           | Servo 8E, yellow                                        |
| 6650                           | LM-Servo 5 cassette                                     |
| 6680                           | LM-Servo 8 cassette                                     |
| 6551T                          | Servo 5E, grey DTS                                      |
| 6552T                          | Servo 5E, blue DTS                                      |
| 6553T                          | Servo 5E, green DTS                                     |
| 6554T                          | Servo 5E, yellow DTS                                    |
| 6581T                          | Servo 8E, grey DTS                                      |
| 6582T                          | Servo 8E, blue DTS                                      |
| 6583T                          | Servo 8E, green DTS                                     |
| 6584T                          | Servo 8E, yellow DTS                                    |
| 810001                         | Cassette for LM-LiftOut & LM-TwistOut                   |
| 6415                           | ServoMax Metal Clips, 2pcs                              |
| 6416                           | ServoMax Univ. Trapper, 2 pcs                           |
| 6417                           | ServoMax lock for Servo 5E/8E                           |

|                        |                                                                                                      |                                                                                                                           |                                                                                                                             |
|------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <b>English (En-US)</b> |                                                                                                      | <b>Bulgarian (BG)</b>                                                                                                     | <b>Croatian (HR)</b>                                                                                                        |
| 1                      | In the table the texts are in English, below you can find the translations when applicable           | В таблицата текстовете са на английски език, по-долу можете да откриете превод, ако е приложимо                           | Tablica sadržiava tekstove na engleskom jeziku, u nastavku možete pronaći odgovarajuće prijevode                            |
| 2                      | Appendix                                                                                             | Допълнение                                                                                                                | Prilog                                                                                                                      |
| 3                      | Intended use: Dental hand instrument for diagnostic operations                                       | Предвидена употреба: Ръчен стоматологичен инструмент за диагностични процедури                                            | Namjena: stomatološki ručni instrument za dijagnostičke postupke                                                            |
| 4                      | Intended use: Dental hand instrument for endodontic operations                                       | Предвидена употреба: Ръчен стоматологичен инструмент за ендодонтски процедури                                             | Namjena: stomatološki ručni instrument za endodonske postupke                                                               |
| 5                      | Intended use: Dental hand instrument for orthodontic operations                                      | Предвидена употреба: Ръчен стоматологичен инструмент за ортодонтски процедури                                             | Namjena: stomatološki ručni instrument za ortodonske postupke                                                               |
| 6                      | Intended use: Dental hand instrument for restorative operations                                      | Предвидена употреба: Ръчен стоматологичен инструмент за възстановителни процедури                                         | Namjena: stomatološki ručni instrument za restauracijske postupke                                                           |
| 7                      | Intended use: Device for storing dental instruments and protecting the instruments and users         | Предвидена употреба: Изделие за съхранение на стоматологични инструменти и за предпазване на инструментите и ползвателите | Namjena: proizvod za pohranu stomatoloških instrumenata i zaštitu instrumenata i korisnika                                  |
| 8                      | Intended use: Removable orthodontic appliance                                                        | Предвидена употреба: Подвижен ортодонтски апарат                                                                          | Namjena: mobilna ortodonska naprava                                                                                         |
| 9                      | MDR Class I based on rule 1                                                                          | Клас I въз основа на правило 1 от Регламента за медицинските изделия                                                      | Medicinski proizvodi I. klase na temelju Pravila 1. Uredbe o medicinskim proizvodima                                        |
| 10                     | MDR Class I based on rule 5                                                                          | Клас I въз основа на правило 5 от Регламента за медицинските изделия                                                      | Medicinski proizvodi I. klase na temelju Pravila 5. Uredbe o medicinskim proizvodima                                        |
| 11                     | Product code                                                                                         | Код на продукта                                                                                                           | Kód proizvoda                                                                                                               |
| 12                     | Basic UDI                                                                                            | Базов UDI                                                                                                                 | Osnovni UDI (Jedinstvena identifikacija proizvoda)                                                                          |
| 13                     | Code / Catalogue number                                                                              | Код/каталожен номер                                                                                                       | Šifra / kataloški broj                                                                                                      |
| 14                     | Trade Name                                                                                           | Търговско наименование                                                                                                    | Trgovački naziv                                                                                                             |
| 15                     | Revision                                                                                             | Редакция                                                                                                                  | Revizija                                                                                                                    |
| 16                     | Non-cutting restorative instruments                                                                  | Нережещи инструменти за възстановяване                                                                                    | Instrumenti za restauraciju koji nisu namijenjeni za rezanje                                                                |
| 17                     | Removable orthodontic appliance                                                                      | Подвижен ортодонтски апарат                                                                                               | mobilna ortodonska naprava                                                                                                  |
| <b>Czech (CS)</b>      |                                                                                                      | <b>Danish (DA)</b>                                                                                                        | <b>Dutch (NL)</b>                                                                                                           |
| 1                      | Text tabulky je v angličtině, příslušné překlady najdete níže                                        | Teksten er på engelsk i skemaet. Oversættelserne kan findes nedenfor, når det er relevant.                                | De tabel bevat Engelse teksten met indien van toepassing daaronder een vertaling                                            |
| 2                      | Dodatek                                                                                              | Bilag                                                                                                                     | Bijlage                                                                                                                     |
| 3                      | Účel použití: Ruční dentální nástroj pro diagnostické výkony                                         | Tilsigtet anvendelse: Tandkirurgisk håndinstrument til diagnostik                                                         | Beoogd gebruik: tandheelkundig handinstrument voor diagnostische ingrepen                                                   |
| 4                      | Účel použití: Ruční dentální nástroj pro endodontické výkony                                         | Tilsigtet anvendelse: Tandkirurgisk håndinstrument til endodonti                                                          | Beoogd gebruik: tandheelkundig handinstrument voor endodontische ingrepen                                                   |
| 5                      | Účel použití: Ruční dentální nástroj pro ortodontické výkony                                         | Tilsigtet anvendelse: Kirurgisk håndinstrument til ortodonti                                                              | Beoogd gebruik: tandheelkundig handinstrument voor orthodontische ingrepen                                                  |
| 6                      | Účel použití: Ruční dentální nástroj pro záchovné výkony                                             | Tilsigtet anvendelse: Tandkirurgisk håndinstrument til retableringsbrug                                                   | Beoogd gebruik: tandheelkundig handinstrument voor restauratieve ingrepen                                                   |
| 7                      | Účel použití: Zařízení pro skladování dentálních nástrojů a ochranu nástrojů a uživatelů             | Tilsigtet anvendelse: Anordning til opbevaring af tandlægeinstrumenter og beskyttelse af instrumenterne og brugerne       | Beoogd gebruik: hulpmiddel voor opslag van tandheelkundige instrumenten, beschermt instrumenten en gebruikers               |
| 8                      | Účel použití: Snímatelné ortodontické pomůcky                                                        | Tilsigtet anvendelse: Aftagelig tandbøjle                                                                                 | Beoogd gebruik: verwijderbaar orthodontisch hulpmiddel                                                                      |
| 9                      | MDR třída I podle pravidla 1                                                                         | MDR Klasse I baseret på regel 1                                                                                           | MDR-klasse I op basis van regel 1                                                                                           |
| 10                     | MDR třída I podle pravidla 5                                                                         | MDR-klasse I baseret på regel 5                                                                                           | MDR-klasse I op basis van regel 5                                                                                           |
| 11                     | Kód produktu                                                                                         | Produktkode                                                                                                               | Productcode                                                                                                                 |
| 12                     | Základní jedinečný identifikátor zdravotnického prostředku                                           | Grundlæggende UDI                                                                                                         | Basis-UDI                                                                                                                   |
| 13                     | Kód / katalogové číslo                                                                               | Kode/katalognummer                                                                                                        | Code/catalogusnummer                                                                                                        |
| 14                     | Obchodní název                                                                                       | Handelsnavn                                                                                                               | Handelsnaam                                                                                                                 |
| 15                     | Verze                                                                                                | Revision                                                                                                                  | Herziening                                                                                                                  |
| 16                     | Neřezající záchovné nástroje                                                                         | Ikke-skærende retableringsinstrumenter                                                                                    | Niet-snijdende restauratieve instrumenten                                                                                   |
| 17                     | Snímatelné ortodontické pomůcky                                                                      | Aftagelig tandbøjle                                                                                                       | verwijderbaar orthodontisch hulpmiddel                                                                                      |
| <b>Estonian (ET)</b>   |                                                                                                      | <b>Finnish (FI)</b>                                                                                                       | <b>French (FR)</b>                                                                                                          |
| 1                      | Tabelitekstid on inglise keeles, altpoolt leiata olemasolevad tõlked                                 | Taulukon teksti on englanniksi, alla ovat soveltuvat käännökset                                                           | Les textes sont en anglais dans le tableau. Vous trouverez ci-dessous les traductions, le cas échéant                       |
| 2                      | Lisa                                                                                                 | Liite                                                                                                                     | Annexe                                                                                                                      |
| 3                      | Sihotstarve: hambaraviinstrument diagnostikatoimingute jaoks                                         | Käyttötarkoitus: Diagnostisissa toimenpiteissä käytettävä hammaslääketieteellinen käsikäyttöinen instrumentti             | Usage prévu : Instrument dentaire à main pour opérations diagnostiques                                                      |
| 4                      | Sihotstarve: hambaraviinstrument endodontiliste toimingute jaoks                                     | Käyttötarkoitus: Endodontisissa toimenpiteissä käytettävä hammaslääketieteellinen käsikäyttöinen instrumentti             | Usage prévu : Instrument dentaire à main pour opérations d'endodontie                                                       |
| 5                      | Sihotstarve: hambaraviinstrument ortodontiliste toimingute jaoks                                     | Käyttötarkoitus: Ortodontisissa toimenpiteissä käytettävä hammaslääketieteellinen käsikäyttöinen instrumentti             | Usage prévu : Instrument dentaire à main pour opérations d'orthodontie                                                      |
| 6                      | Sihotstarve: hambaraviinstrument resuratsioontoimingute jaoks                                        | Käyttötarkoitus: Paikkaustoimenpiteissä käytettävä hammaslääketieteellinen käsikäyttöinen instrumentti                    | Usage prévu : Instrument dentaire à main pour opérations de restauration                                                    |
| 7                      | Sihotstarve: seade hambaraviinstrumentide hoiustamiseks ja instrumentide ning kasutajate kaitsmiseks | Käyttötarkoitus: Laite hammaslääketieteellisten instrumenttien säilytykseen ja instrumentin ja käyttäjien suojaamiseen    | Usage prévu : Dispositif destiné au stockage d'instruments dentaires et à la protection des instruments et des utilisateurs |
| 8                      | Sihotstarve: eemaldatav ortodontiline vahend                                                         | Käyttötarkoitus: Poistettavat oikomiskojeet                                                                               | Usage prévu : Appareil orthodontique amovible                                                                               |
| 9                      | MDR-i klass I reegli 1 alusel                                                                        | Luokan I lääkinnällinen laite säännön 1 mukaan                                                                            | RDM de classe I d'après la règle 1                                                                                          |
| 10                     | MDR-i klass I reegli 5 alusel                                                                        | Luokan I lääkinnällinen laite säännön 5 mukaan                                                                            | RDM de classe I d'après la règle 5                                                                                          |
| 11                     | Tootekood                                                                                            | Tuotekoodi                                                                                                                | Code du produit                                                                                                             |
| 12                     | Põhiline UDI                                                                                         | Yksilöllinen laitetunniste                                                                                                | IUD de base                                                                                                                 |
| 13                     | Kood/katalooginumber                                                                                 | Koodi/luettelonumero                                                                                                      | Code / Numéro de catalogue                                                                                                  |
| 14                     | Kaubanimi                                                                                            | Kauppanimi                                                                                                                | Nom commercial                                                                                                              |
| 15                     | Redaktsioon                                                                                          | Versio                                                                                                                    | Révision                                                                                                                    |
| 16                     | Mitteloikavad restaureerimisinstrumentid                                                             | Leikkaamattomat paikkausinstrumentit                                                                                      | Instruments de restauration non tranchants                                                                                  |
| 17                     | eemaldatav ortodontiline vahend                                                                      | Poistettavat oikomiskojeet                                                                                                | Appareil orthodontique amovible                                                                                             |



**Slovak (SK)**

- 1 V tabulke sú texty v angličtine, nižšie nájdete prípadne preklady
- 2 Dodatok
- 3 Určené použitie: Zubársky ručný nástroj na diagnostické zákroky
- 4 Určené použitie: Zubársky ručný nástroj na endodontické zákroky
- 5 Určené použitie: Zubársky ručný nástroj na ortodontické zákroky
- 6 Určené použitie: Zubársky ručný nástroj na restoratívne zákroky
- 7 Určené použitie: Zariadenie na uchovávanie zubárskych nástrojov a ochranu nástrojov a používateľov
- 8 Určené použitie: Odstrániteľné ortodontické nástroje
- 9 MDR trieda I na základe pravidla 1
- 10 MDR trieda I na základe pravidla 5
- 11 Kód produktu
- 12 Podstawowy UDI
- 13 Kod / numer katalogowy
- 14 Nazwa handlowa
- 15 Wersja
- 16 Nerežúce restoratívne nástroje
- 17 Odstrániteľné ortodontické nástroje

**Swedish (SV)**

- 1 I tabellen finns texterna på engelska, nedan kan du hitta översättningarna när det är tillämpligt
- 2 Bilaga
- 3 Avsedd användning: Dentalhandinstrument för diagnostiska arbeten
- 4 Avsedd användning: Dentalhandinstrument för endodontiska arbeten
- 5 Avsedd användning: Dentalhandinstrument för ortodontiska arbeten
- 6 Avsedd användning: Dentalhandinstrument för återställande operationer
- 7 Avsedd användning: Enhet för förvaring av tandinstrument och skydd av instrument och användare
- 8 Avsedd användning: Avtagbar ortodontisk apparat
- 9 MDR klass I baserat på regel 1
- 10 MDR klass I baserat på regel 5
- 11 Produktkod
- 12 Grundläggande UDI
- 13 Kod / Katalognummer
- 14 Handelsnamn
- 15 Revision
- 16 Icke-skärande återställande instrument
- 17 Avtagbar ortodontisk apparat

**Slovenian (SL)**

- Besedila v tabeli so v angleščini, v nadaljevanju lahko najdete prevode.
- Dodatek
- Predvidena uporaba: zobozdravstveni ročni instrument za diagnostične operacije
- Predvidena uporaba: zobozdravstveni ročni instrument za endodontske operacije
- Predvidena uporaba: zobozdravstveni ročni instrument za ortodontske operacije
- Predvidena uporaba: zobozdravstveni ročni instrument za restavracijske operacije
- Predvidena uporaba: pripomoček za shranjevanje zobozdravstvenih instrumentov ter zaščito instrumentov in uporabnikov
- Predvidena uporaba: snemljiv ortodontski pripomoček
- Uredba o medicinskih pripomočkih razreda I na osnovi pravila 1
- Uredba o medicinskih pripomočkih razreda I na osnovi pravila 5
- Koda izdelka
- UDI básica
- Código/Número do catálogo
- Designação comercial
- Revisão
- Restavracijski instrumenti brez rezila
- snemljiv ortodontski pripomoček

**Spanish (ES)**

- En la tabla aparece el texto en inglés. A continuación, encontrará las traducciones cuando proceda
- Apéndice
- Uso previsto: instrumento dental manual para operaciones de diagnóstico
- Uso previsto: instrumento dental manual para operaciones de endodoncia
- Uso previsto: instrumento dental manual para operaciones de ortodoncia
- Uso previsto: instrumento dental manual para operaciones de reparación
- Uso previsto: dispositivo para almacenar instrumental odontológico y proteger los instrumentos y a los usuarios
- Uso previsto: aparato de ortodoncia extraíble
- Reglamento sobre dispositivos médicos de clase I basado en la regla 1
- Reglamento sobre dispositivos médicos de clase I basado en la regla 5
- Código de producto
- Grundläggande UDI
- Kod / Katalognummer
- Handelsnamn
- Revision
- Instrumentos no cortantes para la reparación
- aparato de ortodoncia extraíble