By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 00847**

Issued To: **Kerr Corporation,**
Also Doing Business as
Pentron Clinical
1717 West Collins Avenue
Orange
California 92867
USA

In respect of:

The manufacture of endodontic materials, dental composite materials and accessories, dental adhesives, cements, dental sealants, fiber posts, and associated sterile and non-sterile dental and endodontic instruments, finishing and polishing instruments for attachment to an active device.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1995-08-29** Date: **2021-04-30** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00847**
Date:	**2021-04-30**
Issued To:	**Kerr Corporation,** **Also Doing Business as** **Pentron Clinical** **1717 West Collins Avenue** **Orange** **California 92867** **USA**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 1000 S. Sarah Place Ontario California 91761 USA	**Gamma Irradiation**
Kerr Italia S.r.l. Via Passanti, 174 Scafati Salerno 84018 Italy	**EU Representative** **Labelling** **Manufacture** **Packaging**
KerrHawe S.A. Via Strecce 4 Bioggio 6934 Switzerland	**Manufacture**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00847**
Date:	**2021-04-30**
Issued To:	**Kerr Corporation, Also Doing Business as Pentron Clinical 1717 West Collins Avenue Orange California 92867 USA**

Subcontractor:	**Service(s) supplied**
Life Science Outsourcing, Inc. 830 Challenger Street Brea California 92821 USA	**Control of Sterilization** **Packaging**
Meta Biomed Vina One Member Limited Liability Company Lot N-1 B, No.4 Road Extended Long Hau Industrial Park, Hamlet 3 Long Hau Commune Can Giuoc District Long An Province Vietnam	**Labelling** **Manufacture** **Packaging**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 00847**
Date:	**2021-04-30**
Issued To:	**Kerr Corporation,** **Also Doing Business as** **Pentron Clinical** **1717 West Collins Avenue** **Orange** **California 92867** **USA**

Subcontractor:	**Service(s) supplied**
Ormex S. de R.L. de C.V. A Subsidiary of Ormco Corporation Calle 21 No. 1103 AMP CD Industrial Uman Yucatan 97390 Mexico	**Labelling** **Manufacture** **Packaging**
SDS de Mexico S. de R.L. de C.V., A Subsidiary of Ormco Corporation Circuito Sur No. 31 Parque Industrial Nelson Mexicali Baja California C.P.21395 Mexico	**Labelling** **Manufacture** **Packaging**
SpofaDental a.s Markova 238 506 01 Jicin Czech Republic	**EU Representative** **Labelling** **Manufacture** **Packaging**

...making excellence a habit.™

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 00847**

Date: **2021-04-30**

Issued To: **Kerr Corporation,**
Also Doing Business as
Pentron Clinical
1717 West Collins Avenue
Orange
California 92867
USA

Date	Reference Number	Action
29 August 1995	-	First issued.
05 November 1997	-	Address change.
19 November 2004	-	Revised wording of scope from 'dental composite restorative materials' to 'dental composite restorative systems'. Certificate renewal and reissue in new format.
05 July 2006	-	Correction to company name from Kerr Dental Materials Centre to Kerr Corporation.
07 September 2009	7437306	Addition of 'Kerr Italia, SpA' as EU Representative Certificate renewal.
05 November 2009	7452138	Company name changed, addition of "Also Doing Business as Pentron Clinical" Addition of 3 new subcontractors, "Pentron Clinical Technologies, LLC" for manufacturing, "SDS de Mexico SA de C.V" for packaging, and CEpartner4U for EU Rep. subcontractor activities Changed the subcontractor name for the Kerr EU rep from Kerr Italia Spa to Kerr Italia S.r.l.
26 October 2010	7596167	Clarification of scope and removal of the subcontractor Pentron Clinical Technologies, LLC, 68 North Plains Industrial Road, Wallingford, CT 06492, USA.
27 August 2014	8166389	Certificate Renewal, removal of CEPartner4U and addition of "SpofaDental" as EU representative for Pentron product lines.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 00847**

Date: **2021-04-30**

Issued To: **Kerr Corporation,**
Also Doing Business as
Pentron Clinical
1717 West Collins Avenue
Orange
California 92867
USA

Date	Reference Number	Action
17 December 2015	8432946	Addition of Dux Dental, Oxnard, California and Kerr Italia S.r.l, Salerno, Italy for the activity manufacture.
01 November 2017	8787277	Addition of Significant Subcontractors: • Plexus (Xiamen) Co., Ltd., No.6 Xiangxing 2 Road, Modern Logistics Zone (Free Trade Zone) Xiamen City, Fujian Province, 361006, China for Manufacture, Packaging and Control Sterilization activities. • Anhui Tiankang Medical Technology Co., Ltd. No. 228 Weiyi Road Economic Development Zone Tianchang City, 239300 Anhui China for Sterilization activity Expansion of scope to include "EndoVac Pure with sterile tip attachments".
26 June 2018	8926842	Addition of Significant Subcontractors related to the manufacturing and sterilization of Class IIa Endodontic Files: • Ormex S. de R. L. de C. V., Uman Yucatan 97390 Mexico for Manufacture • Life Science Outsourcing, Inc., 830 Challenger Street, Brea, CA 92821, USA for Packaging & Control of Sterilization • Isomedix Operations, Inc., 1000 S. Sarah Place, Ontario, California, 91761, USA for Gamma Irradiation Alignment of scope of certificate to appropriately represent products covered.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 00847**

Date: **2021-04-30**

Issued To: **Kerr Corporation,**
Also Doing Business as
Pentron Clinical
1717 West Collins Avenue
Orange
California 92867
USA

Date	Reference Number	Action
15 January 2019	7946170	Traceable to NB 0086.
16 May 2019	9767307	Removal of Endovac Pure system from the scope. Removal of three subcontractors: Dux Dental, Anhui Tiankang Medical and Plexus (Xiamen) Co. Ltd.
27 August 2019	3054471	Certificate Renewal.
05 October 2020	3252057	Clarification of scope to include "adhesives" Addition of Subcontractor, Meta Biomed Vina One Member Limited Liability Company Lot N-1 B, No. 4 Road Extended Long Hau Industrial Park, Hamlet 3, Long Hau Commune, Can Giuoc District, Long An Province, Vietnam Clarification of services supplied by subcontractors, Kerr Italia, Ormex and SDS de Mexico.
17 March 2021	3387291	Expand scope to include "and polishing instruments for attachment to an active device" Addition of Subcontractor, KerrHawe S.A. Via Strecce 4 Bioggio 6934 Switzerland Change address of EU Rep Kerr Italia S.r.l. to, Kerr Italia S.r.l Via Passanti, 174 Scafati (SA) 84018, Italy.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 00847**

Date: **2021-04-30**

Issued To: **Kerr Corporation,**
Also Doing Business as
Pentron Clinical
1717 West Collins Avenue
Orange
California 92867
USA

Date	Reference Number	Action
Current	3421300	Expand scope to add "finishing" Added "Manufacture", "Labelling", "Packaging" to services supplied for subcontractor: SpofaDental a.s. Markova 238 506 01 Jicin Czech Republic

Kerr Italia S.r.l.
Via Passanti, 174
Scafati (SA)
84018
Italy

16-Mar-2024

Notified Body Confirmation Letter

Reference: EU2023-607/780893

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Kerr Italia S.r.l.
Via Passanti, 174
Scafati (SA)
84018
Italy

SRN Number (if available): IT-MF-000007768

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Seal-Tight	Class IIa	N/A	MDD Certificate #CE 02118 expiry date: 2023-10-01; NB#2797
Optibond eXTRa Universal	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
OptiBond Universal	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Bond 1	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Bond 1 SF	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Optibond FL	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Optibond Solo Plus	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Silane Primer	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Silane	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
OptiBond Gel Etchant	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Etching Gel	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Herculite XRV Ultra Flow	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Vertise Flow	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Harmonize	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
SonicFill 2	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Point 4	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Revolution Formula 2	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Premise	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
SimpliShade (Shades: Light, Medium, Dark, Universal Opaque)	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
OptiShade (Shades: Light, Medium, Dark, Universal Opaque)	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
SonicFill 3	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Artiste	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Herculite XRV	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Herculite XRV Ultra	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Premise Flowable	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
SimpliShade (Shade: Bleach White)	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
OptiShade (Shade: Bleach White)	Class IIa	N/A	MDD Certificate #CE 00847

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			expiry date: 2024-05-26; NB#2797
Herculite Classic	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Flow-It ALC	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Fusio	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Kolor Plus	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Neofil	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Simile	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Build-It FR	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
SonicFill 3 Intro Kit Procedure Pack	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
FibreKleer 4X Posts	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
FibreKor Posts	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Autofit Feather Tip Gutta Percha	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Autofit Greater Taper Gutta Percha	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Autofit Backfill Gutta Percha	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
K3 Gutta Percha	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
K3 Feather Tip Gutta Percha	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
TF Gutta Percha	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
TF Adaptive Gutta Percha	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
ISO Color Coded Gutta Percha	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Accessory Gutta Percha	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Elements Gutta Percha Cartridge	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Sealapex	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Pulp Canal Sealer	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Tubli-Seal	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Autofit Greater Taper Paper Points	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Non-Standard Paper Points	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Standard Paper Points	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
TF Adaptive Paper Points	Class IIa	N/A	MDD Certificate #CE 00847

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			expiry date: 2024-05-26; NB#2797
Breeze	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Cement-It	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Life	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Maxcem Elite	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Maxcem Elite Chroma	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Mojo	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
NX3	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
dextaCem	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
TempBond Clear	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
TempSpan C&B	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Temp-Bond	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Temp-Bond NE	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
TAB 2000	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797 and

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			MDD Certificate #CE 01220 Expiry date: 2024-02-28; NB#2797
Zone A1	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
ZoneFree	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Zone	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
ZenFlex Files	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
TF - Engine Files	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
TFA - Engine Files	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Traverse File	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
K3 - Engine Files	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
K3XF - Engine Files	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Quantec - Engine Files	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Heat Pluggers	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Post Drills	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Prophy Mandrel	Class IIa	N/A	MDD Certificate #CE 00847

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			expiry date: 2024-05-26; NB#2797
OptiDisc Mandrel	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Polishing Brush	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Miniature Polishing Brush	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Pro-Brush	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Pro-Cup	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Pro-Cup Junior	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Occlubrush	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
OptiShine	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
IndentoBrush	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
AABA-Dental Universal	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Identoflex Dental Universal Prepolisher	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
HiLuster Plus Polishing System	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Identoflex Composite Polisher	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Identoflex Diamond Composite Polishers	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Opti1Step Polisher	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
OptiClean	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
GlossPLUS Polishing System	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Dia1Step	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
JDENT Polerer Polisher	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Identoflex Diamond Ceramic Polishers	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Identoflex Diamond Porcelain/Ceramic NG	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Identoflex Gold and Amalgam Polishers	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
BLUWHITE (Diamond)	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
JET (Diamond)	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
JET (Carbide)	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
PENTRON (Carbide)	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Rotary Burs – Diamond and Carbide	Class IIa	N/A	MDD Certificate #CE 00847

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			expiry date: 2024-05-26; NB#2797
OptiDisc	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
Polishing Assorted Kit	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
ProHALOFlow^{evo}	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
ProHALO^{evo}	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
ProKLEEP^{evo}	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797
ProTIXO^{evo}	Class IIa	N/A	MDD Certificate #CE 00847 expiry date: 2024-05-26; NB#2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/03/16	Initial issue