EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 783335 R000

Manufacturer: Kerr Italia S.r.l.

Address:
Via Passanti, 174
Scafati (SA)
84018
Italy

Single Registration Number: IT-MF-000007768

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2024-01-10**

Current Issue Date: **2024-01-10**

Starting Validity Date: **2024-01-10**

Expiry Date: **2029-01-09**

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 783335 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile and non-sterile dental and endodontic instruments	Class IIa
Implantable dental materials	Class IIa, implantable
Non-sterile reusable endodontic instruments	Class Ir
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

First Issue Date: **2024-01-10**

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3817666	Issued

First Issue Date: **2024-01-10**

Current Issue Date: **2024-01-10**

Starting Validity Date: **2024-01-10**

Expiry Date: **2029-01-09**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Kerr Italia S.r.l.
Manufacturer address and contact details	Via Passanti, 174 Scafati (SA), 84018, Italy
Single Registration Number (SRN) (if available)	IT-MF-000007768

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	BSI ☒ See attached schedule
Notified body number (if applicable)	2797 ☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule Kerr Italia S.r.l. MDD EC Certificate (CE 01220): 2024-02-28 Kerr Corporation, Also Doing Business as Pentron Clinical (CE 00847)
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Kerr Italia S.r.l. MDD EC Certificate (CE 01220): 2024-02-28

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

	Kerr Corporation, Also Doing Business as Pentron Clinical (CE 00847): 2024-05-26 ☒ See attached schedule
End date of extended validity/transition period	2028-12-31 ☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐Expired *before* 20 March 2023:

  ☐Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☒Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐A QMS in accordance with Article 10(9) MDR is in place.

☒A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.

- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Kerr Italia S.r.l.

Company Name

Scafati, Italy 03-Apr-2024 | 22:13 CEST

Location **Date**

DocuSigned by:
Jennifer Evans
8DF30BF54302405...

Signature

Jennifer Evans

Name

Vice President, RA/QA Kerr;

Company Officer of Kerr Italia S.r.l.

Title

jennifer.evans@envistaco.com

Contact Email

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Optibond eXTRa Universal	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
OptiBond Universal	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Bond 1	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Bond 1 SF	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
OptiBond FL	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
OptiBond Solo Plus	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Silane Primer	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Silane	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
OptiBond Gel Etchant	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Etching Gel	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Herculite XRV Ultra Flow	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Vertise Flow	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Harmonize	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
SonicFill 2	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Point 4	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Revolution Formula 2	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Premise	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
SimpliShade (Shades: Light, Medium, Dark, Universal Opaque)	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
OptiShade (Shades: Light, Medium, Dark, Universal Opaque)	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
SonicFill 3	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Artiste	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Herculite XRV	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Herculite XRV Ultra	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Premise Flowable	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
SimpliShade (Shade: Bleach White)	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
OptiShade (Shade: Bleach White)	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Herculite Classic	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Flow-It ALC	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Fusio	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Kolor Plus	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Neofil	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Simile	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Build-It FR	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
SonicFill 3 Intro Kit Procedure Pack	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
FibreKleer 4X Posts	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
FibreKor Posts	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable

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Autofit Feather Tip Gutta Percha	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Autofit Greater Taper Gutta Percha	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Autofit Backfill Gutta Percha	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
K3 Gutta Percha	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
K3 Feather Tip Gutta Percha	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
TF Gutta Percha	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
TF Adaptive Gutta Percha	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
ISO Color Coded Gutta Percha	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Accessory Gutta Percha	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Elements Gutta Percha Cartridge	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Sealapex	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Pulp Canal Sealer	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Tubli-Seal	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Autofit Greater Taper Paper Points	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Non-Standard Paper Points	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Standard Paper Points	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
TF Adaptive Paper Points	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Breeze	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Cement-It	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Life	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Maxcem Elite	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Maxcem Elite Chroma	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Mojo	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
NX3	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
dextaCem	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
TempBond Clear	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
TempSpan C&B	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Temp-Bond	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Temp-Bond NE	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
TAB 2000	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Zone A1	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
ZoneFree	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Zone	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
ZenFlex Files	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
TF - Engine Files	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
TFA - Engine Files	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Traverse File	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
K3 - Engine Files	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
K3XF - Engine Files	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Quantec - Engine Files	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Heat Pluggers	CE 00847 And CE 01220	2024-05-26 And 2024-02-28	BSI 2797 And BSI 2797	BSI 2797 And BSI 2797	2028-12-31 And 2028-12-31	Not Applicable
Post Drills	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Hedstrom	Previously MDD Class I with no Notified Body required; Moving to Class Ir.	N/A	N/A	BSI 2797	2028-12-31	Not Applicable
Reamer	Previously MDD Class I with no Notified Body required; Moving to Class Ir.	N/A	N/A	BSI 2797	2028-12-31	Not Applicable
K-Files	Previously MDD Class I with no Notified Body required; Moving to Class Ir.	N/A	N/A	BSI 2797	2028-12-31	Not Applicable
Triple-Flex File	Previously MDD Class I with no Notified Body required; Moving to Class Ir.	N/A	N/A	BSI 2797	2028-12-31	Not Applicable

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
K-Flex File	Previously MDD Class I with no Notified Body required; Moving to Class Ir.	N/A	N/A	BSI 2797	2028-12-31	Not Applicable
Hand Pluggers	Previously MDD Class I with no Notified Body required; Moving to Class Ir.	N/A	N/A	BSI 2797	2028-12-31	Not Applicable
Aluminum Potassium Sulfate Retraction Cord	Previously MDD Class I with no Notified Body required; Moving to Class IIa.	N/A	N/A	BSI 2797	2028-12-31	Not Applicable
Prophy Mandrel	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
OptiDisc Mandrel	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Polishing Brush	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Miniature Polishing Brush	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Pro-Brush	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Pro-Cup	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Pro-Cup Junior	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Occlubrush	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
OptiShine	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
IndentoBrush	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
AABA-Dental Universal	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Identoflex Dental Universal Prepolisher	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
HiLuster Plus Polishing System	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Identoflex Composite Polisher	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Identoflex Diamond Composite Polishers	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Opti1Step Polisher	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
OptiClean	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
GlossPLUS Polishing System	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Dia1Step	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
JDENT Polerer Polisher	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Identoflex Diamond Ceramic Polishers	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Identoflex Diamond Porcelain/Ceramic NG	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Identoflex Gold and Amalgam Polishers	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
BLUWHITE (Diamond)	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
JET (Diamond)	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
JET (Carbide)	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
PENTRON (Carbide)	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Rotary Burs – Diamond and Carbide	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
OptiDisc	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Polishing Assorted Kit	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
ProHALOFlow^{evo}	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
ProHALO^{evo}	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
ProKLEEP^{evo}	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable
ProTIXO^{evo}	CE 00847	2024-05-26	BSI 2797	BSI 2797	2028-12-31	Not Applicable

Attachment A – Directive Certificates

- Kerr Italia S.r.l. MDD EC Certificate (CE 01220): 2024-02-28
- Kerr Corporation, Also Doing Business as Pentron Clinical (CE 00847): 2024-05-26

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EC Certificate - Production Quality Assurance

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

No. **CE 01220**

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

In respect of:

The manufacture of dental adhesives, pit and fissure sealants, cavity lining materials, non-medicated pulp capping materials, dental cements, materials for temporary crowns and bridges and composite dental materials and accessories.

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: **1996-02-29** Date: **2021-03-02** Expiry Date: **2024-02-28**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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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 01220**
Date:	**2021-03-02**
Issued To:	**Kerr Italia S.r.l.** **Via Passanti, 174** **Scafati (SA)** **84018** **Italy**

Subcontractor:	**Service(s) supplied**
Kerr Corporation, Also Doing Business as Pentron Clinical 1717 West Collins Avenue Orange California 92867 USA	**Administration & Complaints** **Regulatory Compliance**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 01220**
Date: **2021-03-02**
Issued To: **Kerr Italia S.r.l.**
Via Passanti, 174
Scafati (SA)
84018
Italy

Certificate History

Date	Reference Number	Action
29 February 1996	-	First issue
16 January 2002	-	Addition of adhesives, sealants, composites and prostheses
03 December 2002	-	Addition of single use endodontic instruments
22 November 2004	-	Change of composite dental materials to dental composite restorative systems, the deletion of Eugenol based, the addition of sealers and deletion of the Torino site as subcontractor due to site closure. Certificate renewal and reissued in new format
10 August 2006	-	Extension to scope, to include single sterile single use hand operated instruments and addition of Gammatom S.r.L to the list of significant sub contractors as Gamma Irradiation
19 December 2006	-	Company name change from "Kerr Italia Spa" to " Kerr Italia S.r.l."
06 March 2009	7215335	Certificate renewal

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 01220**
Date: **2021-03-02**
Issued To: **Kerr Italia S.r.l.**
Via Passanti, 174
Scafati (SA)
84018
Italy

Date	Reference Number	Action
16 February 2012	7802590	Change to Scope from: "The manufacture of dental adhesives, pit and fissure sealants, cavity lining materials, non-medicated pulp capping materials, dental cements, materials for temporary crowns and bridges, temporary filling materials, composite dental materials for direct insertion, fixed and removable prostheses, single use endodontic instruments, endodontic sealers, and sterile single use endodontic instruments To " The manufacture of dental adhesives, pit and fissure sealants, cavity lining materials, non-medicated pulp capping materials, dental cements, materials for temporary crowns and bridges, temporary filling materials, composite dental materials for direct insertion, fixed and removable prostheses, and endodontic sealers" Removal of Gammatom S.r.L as significant sub contractor for gamma irradiation of the obsoleted product line.
26 February 2014	8119653	Certificate renewal Addition of Kerr Corporation, California as subcontractor.
15 January 2019	7779015	Traceable to NB 0086.

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Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 01220**
Date: **2021-03-02**
Issued To: **Kerr Italia S.r.l.**
Via Passanti, 174
Scafati (SA)
84018
Italy

Date	Reference Number	Action
25 February 2019	9633351	Revise to reflect 5 year renewal and reduction of scope.
Current	3389652	Change to street number for legal manufacture's address, from 332 to 174. No change to physical location of legal manufacturer.

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Page 3 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

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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**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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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**

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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**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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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**
Ravelli S.p.A Via Darwin 32/34 Settimo Milanese Milan 20019 Italy	**Packaging**

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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
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 Jicín CZ-506 01 Czech Republic	**EU Representative** **Labelling** **Manufacture** **Packaging**

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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.

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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.

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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.

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Page 3 of 4

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
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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
30 April 2021	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
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
22 June 2021	3333588	Addition of eIFU to meet the requirements of Regulation EU/207/2012.
17 January 2022	3540911	Addition of Subcontractor, KerrHawe S.A. Via Strecce 4 Bioggio 6934 Switzerland
11 May 2022	3564476	Addition of Ravelli S.p.A as subcontractor for packaging.

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11 May 2022

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 00847	93/42/EEC Annex V	3564476	Addition of Ravelli S.p.A as subcontractor for packaging

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl

SUSTAINABLE DEVELOPMENT GOALS

Attachment B – Upclassified Device MDD Declaration of Conformity

- APS Cord
- Hand Files
- Hand Pluggers

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Annex VII EC Declaration of Conformity

Manufacturer Name and Address:	Kerr Corporation 1717 West Collins Avenue Orange, CA 92867, USA
Authorized Representative Name and Address:	Kerr Italia, S.r.l. Via Passanti, 174 Scafati (SA) 84018, Italy
Technical File Name/Number:	Project DUX121 & Technical File R042
Product Tradename(s):	GingiKNIT+, UniBRAID+, GingiBRAID+, and GingiBRAID+ with ShortCut Aluminum Potassium Sulfate Retraction Cords
Device Identification:	See Attachment 1
Classification and Rule(s):	I per Annex IX, Rule 5
Notified Body:	N/A
Notified Body Number:	N/A
Conformity Assessment Procedure & Certificate issued:	Annex VII N/A

Declaration Statement:
We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.

Regulatory Affairs Signature:

May 24, 2022
Issue date

Name: Jennifer Evans
Title: Vice President RA/QA - Consumables

KERR ITALIA S.r.l. - Stabilimento: Via Passanti 174 - 84018 SCAFATI (Salerno)
Tel pbx: (081) 8508311 Fax: (081) 8639083 - 8637076
Cap. Versato. Euro 516.480,00 Codice Fiscale: 00852620152 Partita Iva: 06313070630

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Aluminum Potassium Sulfate Retraction Cords – Attachment 1
to Annex VII EC Declaration of Conformity

REF	Description
GingiBRAID+	
13210	GingiBRAID+ 0a Aluminum Potassium Sulfate
13211	GingiBRAID+ 1a Aluminum Potassium Sulfate
13212	GingiBRAID+ 2a Aluminum Potassium Sulfate
13213	GingiBRAID+ 3a Aluminum Potassium Sulfate
GingiBRAID+ with ShortCut	
13730	GingiBRAID+ with ShortCut 0a Aluminum Potassium Sulfate
13731	GingiBRAID+ with ShortCut 1a Aluminum Potassium Sulfate
13732	GingiBRAID+ with ShortCut 2a Aluminum Potassium Sulfate
GingiKNIT+	
13508	GingiKNIT+ 000a Aluminum Potassium Sulfate
13509	GingiKNIT+ 00a Aluminum Potassium Sulfate
13510	GingiKNIT+ 0a Aluminum Potassium Sulfate
13511	GingiKNIT+ 1a Aluminum Potassium Sulfate
13512	GingiKNIT+ 2a Aluminum Potassium Sulfate
UniBRAID+	
13360DX	UniBRAID+ 0a Aluminum Potassium Sulfate, 50ct
13361	UniBRAID+ 1a Aluminum Potassium Sulfate, 50ct
13362	UniBRAID+ 2a Aluminum Potassium Sulfate, 50ct

KERR ITALIA S.r.l. - Stabilimento: Via Passanti 174 - 84018 SCAFATI (Salerno)
Tel pbx: (081) 8508311 Fax: (081) 8639083 - 8637076
Cap. Versato. Euro 516.480,00 Codice Fiscale: 00852620152 Partita Iva: 06313070630

Kerr

Signature Manifest

Document Number: DC-CETF-000193 **Revision:** 4
Title: EU DoC APS Retraction Cords (MDD)

All dates and times are in Pacific Standard Time.

EU DoC - APS Retraction Cords (MDD)

01. Modify Approvers for Step (02.Approve)

Name/Signature	Title	Date	Meaning/Reason
HAIYAN WEI (HAIYAN.WEI)		24 May 2022, 04:12:37 PM	Reviewed

02. Approve

Name/Signature	Title	Date	Meaning/Reason
HAIYAN WEI (HAIYAN.WEI)		24 May 2022, 04:13:16 PM	Approved

03. Release

Name/Signature	Title	Date	Meaning/Reason
HAIYAN WEI (HAIYAN.WEI)		24 May 2022, 04:13:52 PM	Approved

04. Distribution/Notification

Name/Signature	Title	Date	Meaning/Reason
HAIYAN WEI (HAIYAN.WEI)		24 May 2022, 04:13:52 PM	Email Sent
Mark Anderson (MARK.ANDERSON)		24 May 2022, 04:13:52 PM	Email Sent

KERR ITALIA S.r.l. - Stabilimento: Via Passanti 174 - 84018 SCAFATI (Salerno)
Tel pbx: (081) 8508311 Fax: (081) 8639083 - 8637076
Cap. Versato. Euro 516.480,00 Codice Fiscale: 00852620152 Partita Iva: 06313070630

Kerr

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Annex VII EC Declaration of Conformity

Manufacturer Name and Address:	Kerr Corporation also trading as Pentron Clinical 1717 West Collins Avenue Orange, CA 92867 USA
Authorized Representative Name and Address:	Kerr Italia, S.r.l. Via Passanti, 174 84018 Scafati (S.A.), Italy
Technical File Name/Number:	Endodontic Hand Files/Endo-007
Product Tradename(s):	K-File, K-Flex, Triple-Flex, Hedstrom, Reamers
Device Identification:	see Attachment 1
Classification and Rule(s):	Class I, Rule 6
Notified Body: **Notified Body Number:**	N/A N/A
Conformity Assessment Procedure & Certificate Issued:	Annex VII CE Certificate N/A

Declaration Statement:
We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.

Regulatory Affairs Signature:

13 July 2021
Issue date

Name: Mark Dzendzel
Title: Director, Quality Assurance Systems

KERR ITALIA S.r.l. - Stabilimento: Via Passanti 174 - 84018 SCAFATI (Salerno)
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Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
12766	Hedstrom, 21mm Size 15, 6-Pack
12769	Hedstrom, 21mm Size 20, 6-Pack
12772	Hedstrom, 21mm Size 25, 6-Pack
12775	Hedstrom, 21mm Size 30, 6-Pack
12778	Hedstrom, 21mm Size 35, 6-Pack
12781	Hedstrom, 21mm Size 40, 6-Pack
12784	Hedstrom, 21mm Size 45, 6-Pack
12787	Hedstrom, 21mm Size 50, 6-Pack
12790	Hedstrom, 21mm Size 55, 6-Pack
12793	Hedstrom, 21mm Size 60, 6-Pack
12796	Hedstrom, 21mm Size 70, 6-Pack
11344	Hedstrom, 25mm Size 15, 6-Pack
11345	Hedstrom, 25mm Size 20, 6-Pack
11346	Hedstrom, 25mm Size 25, 6-Pack
11347	Hedstrom, 25mm Size 30, 6-Pack
11348	Hedstrom, 25mm Size 35, 6-Pack
11349	Hedstrom, 25mm Size 40, 6-Pack
11350	Hedstrom, 25mm Size 45, 6-Pack
11351	Hedstrom, 25mm Size 50, 6-Pack
11352	Hedstrom, 25mm Size 55, 6-Pack
11353	Hedstrom, 25mm Size 60, 6-Pack
11354	Hedstrom, 25mm Size 70, 6-Pack
12814	Hedstrom, 30mm Size 15, 6-Pack
12817	Hedstrom, 30mm Size 20, 6-Pack
12820	Hedstrom, 30mm Size 25, 6-Pack
12823	Hedstrom, 30mm Size 30, 6-Pack
12826	Hedstrom, 30mm Size 35, 6-Pack
12829	Hedstrom, 30mm Size 40, 6-Pack
12832	Hedstrom, 30mm Size 45, 6-Pack
12835	Hedstrom, 30mm Size 50, 6-Pack
12838	Hedstrom, 30mm Size 55, 6-Pack
12841	Hedstrom, 30mm Size 60, 6-Pack
13278	Hedstrom, 30mm Size 70, 6-Pack
12809	Hedstrom, 21mm Asst 15/40, 6-Pack
12810	Hedstrom, 21mm Asst 45/80, 6-Pack
11359	Hedstrom, 25mm Asst 15/40, 6-Pack
11360	Hedstrom, 25mm Asst 45/80, 6-Pack
13291	Hedstrom, 30mm Asst 15/40, 6-Pack
13292	Hedstrom, 30mm Asst 45/80, 6-Pack
61684	Hedstrom, 21mm Size 80, 6-Pack
61702	Hedstrom, 25mm Size 80, 6-Pack
61720	Hedstrom, 30mm Size 80, 6-Pack

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Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
14127	K-File, 21mm Size 08, 6-Pack
06003	K-File, 21mm Size 10, 6-Pack
06004	K-File, 21mm Size 15, 6-Pack
06005	K-File, 21mm Size 20, 6-Pack
06014	K-File, 21mm Size 25, 6-Pack
06015	K-File, 21mm Size 30, 6-Pack
06016	K-File, 21mm Size 35, 6-Pack
06019	K-File, 21mm Size 40, 6-Pack
06020	K-File, 21mm Size 45, 6-Pack
06021	K-File, 21mm Size 50, 6-Pack
06022	K-File, 21mm Size 55, 6-Pack
06023	K-File, 21mm Size 60, 6-Pack
06024	K-File, 21mm Size 70, 6-Pack
06026	K-File, 21mm Size 80, 6-Pack
61363	K-File, 21mm Asst. 45-70 PK-6
821-8021	K-File, 21mm Asst 15/40, 6-Pack
821-8121	K-File, 21mm Asst 45/80, 6-Pack
14128	K-File, 25mm Size 08, 6-Pack
06062	K-File, 25mm Size 10, 6-Pack
06063	K-File, 25mm Size 15, 6-Pack
06064	K-File, 25mm Size 20, 6-Pack
06065	K-File, 25mm Size 25, 6-Pack
06066	K-File, 25mm Size 30, 6-Pack
06067	K-File, 25mm Size 35, 6-Pack
06069	K-File, 25mm Size 40, 6-Pack
06074	K-File, 25mm Size 45, 6-Pack
06075	K-File, 25mm Size 50, 6-Pack
06076	K-File, 25mm Size 55, 6-Pack
06077	K-File, 25mm Size 60, 6-Pack
06085	K-File, 25mm Size 70, 6-Pack
06099	K-File, 25mm Size 80, 6-Pack
821-8025	K-File, 25mm Asst 15/40, 6-Pack
821-8125	K-File, 25mm Asst 45/80, 6-Pack
14129	K-File, 30mm Size 08, 6-Pack
06151	K-File, 30mm Size 10, 6-Pack
06152	K-File, 30mm Size 15, 6-Pack
06153	K-File, 30mm Size 20, 6-Pack
06155	K-File, 30mm Size 25, 6-Pack
06156	K-File, 30mm Size 30, 6-Pack
06157	K-File, 30mm Size 35, 6-Pack
06159	K-File, 30mm Size 40, 6-Pack
06160	K-File, 30mm Size 45, 6-Pack
06161	K-File, 30mm Size 50, 6-Pack
06162	K-File, 30mm Size 55, 6-Pack
06163	K-File, 30mm Size 60, 6-Pack
06166	K-File, 30mm Size 70, 6-Pack
06170	K-File, 30mm Size 80, 6-Pack

INFOCARD# DC-CETF-000147 - REVISION Rev. 2 , RELEASED ON 13 Jul 2021, STORED AT DC-CE TECH FILE-REL

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Tel pbx: (081) 8508311 Fax: (081) 8639083 - 8637076
Cap. Versato. Euro 516.480,00 Codice Fiscale: 00852620152 Partita Iva: 06313070630

Kerr

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Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	**Description**
821-8030	K-File, 30mm Asst 15/40, 6-Pack
821-8130	K-File, 30mm Asst 45/80, 6-Pack
62249	K-File, 21mm Size 06, 6-Pack
62250	K-File, 25mm Size 06, 6-Pack
62251	K-File, 30mm Size 06, 6-Pack

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Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
15302	K-Flex File, 21mm Size 20, 6-Pack
15306	K-Flex File, 21mm Size 25, 6-Pack
15310	K-Flex File, 21mm Size 30, 6-Pack
15314	K-Flex File, 21mm Size 35, 6-Pack
15318	K-Flex File, 21mm Size 40, 6-Pack
15322	K-Flex File, 21mm Size 45, 6-Pack
15326	K-Flex File, 21mm Size 50, 6-Pack
15330	K-Flex File, 21mm Size 55, 6-Pack
15334	K-Flex File, 21mm Size 60, 6-Pack
15122	K-Flex File, 25mm Size 08, 6-Pack
15126	K-Flex File, 25mm Size 10, 6-Pack
15130	K-Flex File, 25mm Size 15, 6-Pack
15134	K-Flex File, 25mm Size 20, 6-Pack
15138	K-Flex File, 25mm Size 25, 6-Pack
15142	K-Flex File, 25mm Size 30, 6-Pack
15146	K-Flex File, 25mm Size 35, 6-Pack
15150	K-Flex File, 25mm Size 40, 6-Pack
15154	K-Flex File, 25mm Size 45, 6-Pack
15158	K-Flex File, 25mm Size 50, 6-Pack
15162	K-Flex File, 25mm Size 55, 6-Pack
15166	K-Flex File, 25mm Size 60, 6-Pack
15170	K-Flex File, 25mm Size 70, 6-Pack
15174	K-Flex File, 25mm Size 80, 6-Pack
15206	K-Flex File, 30mm Size 08, 6-Pack
15210	K-Flex File, 30mm Size 10, 6-Pack
15214	K-Flex File, 30mm Size 15, 6-Pack
15218	K-Flex File, 30mm Size 20, 6-Pack
15222	K-Flex File, 30mm Size 25, 6-Pack
15226	K-Flex File, 30mm Size 30, 6-Pack
15230	K-Flex File, 30mm Size 35, 6-Pack
15234	K-Flex File, 30mm Size 40, 6-Pack
15238	K-Flex File, 30mm Size 45, 6-Pack
15242	K-Flex File, 30mm Size 50, 6-Pack
15246	K-Flex File, 30mm Size 55, 6-Pack
15250	K-Flex File, 30mm Size 60, 6-Pack
15254	K-Flex File, 30mm Size 70, 6-Pack
15258	K-Flex File, 30mm Size 80, 6-Pack
60120	K-Flex File, 21mm Size 06, 6-Pack
60125	K-FLEX NO. 25 21MM
60141	K-FLEX FILES 21MM SZ 15-40 ASST. PK/6
60142	K-FLEX FILES 21MM SZ 45-60 ASST. PK/6
60144	K-Flex File, 25mm Size 06, 6-Pack
60165	K-FLEX FILES 25MM SZ 15-40 ASST. PK/6
60166	K-FLEX FILES 25MM SZ 45-80 ASST. PK/6
60189	K-FLEX FILES 30MM SZ 15-40 ASST. PK/6

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Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	**Description**
60190	K-FLEX FILES 30MM SZ 45-80 ASST. PK/6
60193	K-Flex File, 30mm Size 06, 6-Pack
821-4021	K-Flex File, 21mm Asst 15/40, 6-Pack
821-4025	K-Flex File, 25mm Asst 15/40, 6-Pack
821-4125	K-Flex File, 25mm Asst 45/80, 6-Pack
821-4030	K-Flex File, 30mm Asst 15/40, 6-Pack
821-4130	K-Flex File, 30mm Asst 45/80, 6-Pack
15290	K-Flex File, 21mm Size 08, 6-Pack
15294	K-Flex File, 21mm Size 10, 6-Pack
15298	K-Flex File, 21mm Size 15, 6-Pack

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Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	Description
25927	Triple-Flex File, 21mm Size 08, 6-pack
25928	Triple-Flex File, 21mm Size 10, 6-pack
25929	Triple-Flex File, 21mm Size 15, 6-pack
25930	Triple-Flex File, 21mm Size 20, 6-pack
25931	Triple-Flex File, 21mm Size 25, 6-pack
25932	Triple-Flex File, 21mm Size 30, 6-pack
25933	Triple-Flex File, 21mm Size 35, 6-pack
25935	Triple-Flex File, 21mm Size 40, 6-pack
25936	Triple-Flex File, 21mm Size 45, 6-pack
25937	Triple-Flex File, 21mm Size 50, 6-pack
25938	Triple-Flex File, 21mm Size 55, 6-pack
25939	Triple-Flex File, 21mm Size 60, 6-pack
25940	Triple-Flex File, 21mm Size 70, 6-pack
25941	Triple-Flex File, 21mm Size 80, 6-pack
25943	Triple-Flex File, 25mm Size 08, 6-pack
25944	Triple-Flex File, 25mm Size 10, 6-pack
25945	Triple-Flex File, 25mm Size 15, 6-pack
25946	Triple-Flex File, 25mm Size 20, 6-pack
25947	Triple-Flex File, 25mm Size 25, 6-pack
25948	Triple-Flex File, 25mm Size 30, 6-pack
25949	Triple-Flex File, 25mm Size 35, 6-pack
25951	Triple-Flex File, 25mm Size 40, 6-pack
25952	Triple-Flex File, 25mm Size 45, 6-pack
25953	Triple-Flex File, 25mm Size 50, 6-pack
25954	Triple-Flex File, 25mm Size 55, 6-pack
25955	Triple-Flex File, 25mm Size 60, 6-pack
25956	Triple-Flex File, 25mm Size 70, 6-pack
25957	Triple-Flex File, 25mm Size 80, 6-pack
25959	Triple-Flex File, 30mm Size 08, 6-pack
25960	Triple-Flex File, 30mm Size 10, 6-pack
25961	Triple-Flex File, 30mm Size 15, 6-pack
25962	Triple-Flex File, 30mm Size 20, 6-pack
25963	Triple-Flex File, 30mm Size 25, 6-pack
25964	Triple-Flex File, 30mm Size 30, 6-pack
25965	Triple-Flex File, 30mm Size 35, 6-pack
25967	Triple-Flex File, 30mm Size 40, 6-pack
25968	Triple-Flex File, 30mm Size 45, 6-pack
25969	Triple-Flex File, 30mm Size 50, 6-pack
25970	Triple-Flex File, 30mm Size 55, 6-pack
25971	Triple-Flex File, 30mm Size 60, 6-pack
25972	Triple-Flex File, 30mm Size 70, 6-pack
25973	Triple-Flex File, 30mm Size 80, 6-pack
821-3021	Triple-Flex File, 21mm Asst 15/40, 6-pack
821-3025	Triple-Flex File, 25mm Asst 15/40, 6-pack
821-3030	Triple-Flex File, 30mm Asst 15/40, 6-pack
821-3121	Triple-Flex File, 21mm Asst 45/80, 6-pack
821-3125	Triple-Flex File, 25mm Asst 45/80, 6-pack
821-3130	Triple-Flex File, 30mm Asst 45/80, 6-pack

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Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	**Description**
14133	Reamer, 21mm Size 08, 6-pack
06029	Reamer, 21mm Size 10, 6-pack
06030	Reamer, 21mm Size 15, 6-pack
06031	Reamer, 21mm Size 20, 6-pack
06032	Reamer, 21mm Size 25, 6-pack
06033	Reamer, 21mm Size 30, 6-pack
06034	Reamer, 21mm Size 35, 6-pack
06038	Reamer, 21mm Size 40, 6-pack
06040	Reamer, 21mm Size 45, 6-pack
14134	Reamer, 25mm Size 08, 6-pack
06110	Reamer, 25mm Size 10, 6-pack
06111	Reamer, 25mm Size 15, 6-pack
06112	Reamer, 25mm Size 20, 6-pack
06120	Reamer, 25mm Size 25, 6-pack
06126	Reamer, 25mm Size 30, 6-pack
06127	Reamer, 25mm Size 35, 6-pack
06131	Reamer, 25mm Size 40, 6-pack
06132	Reamer, 25mm Size 45, 6-pack
821-2021	Reamer, 21mm Asst 15/40, 6-Pack
821-2025	Reamer, 25mm Asst 15/40, 6-Pack
61375	Reamer, 21mm Size 50, 6-pack
61376	Reamer, 21mm Size 55, 6-pack
61377	Reamer, 21mm Size 60, 6-pack
61378	Reamer, 21mm Size 70, 6-pack
61379	Reamer, 21mm Asst 45/70, 6-pack
61407	Reamer, 25mm Size 50, 6-pack
61408	Reamer, 25mm Size 55, 6-pack
61409	Reamer, 25mm Size 60, 6-pack
61410	Reamer, 25mm Size 70, 6-pack
61412	Reamer, 25mm Size 80, 6-pack
61430	Reamer, 30mm Size 10, 6-pack
61431	Reamer, 30mm Size 15, 6-pack
61432	Reamer, 30mm Size 20, 6-pack
61433	Reamer, 30mm Size 25, 6-pack
61434	Reamer, 30mm Size 30, 6-pack
61435	Reamer, 30mm Size 35, 6-pack
61436	Reamer, 30mm Asst 15/40, 6-pack
61437	Reamer, 30mm Size 40, 6-pack
61438	Reamer, 30mm Size 45, 6-pack
61439	Reamer, 30mm Size 50, 6-pack
61440	Reamer, 30mm Size 55, 6-pack
61441	Reamer, 30mm Size 60, 6-pack
61442	Reamer, 30mm Size 70, 6-pack
61443	Reamer, 30mm Asst 45/80, 6-pack
61444	Reamer, 30mm Size 80, 6-pack
62260	Reamer, 30mm Size 08, 6-pack
62252	Reamer, 21mm Size 06, 6-pack

INFOCARD# DC-CETF-000147 - REVISION Rev. 2 , RELEASED ON 13 Jul 2021, STORED AT DC-CE TECH FILE-REL

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Endodontic Hand Files/Endo-007 - Attachment 1 to Annex VII EC Declaration of Conformity	
REF	**Description**
62253	Reamer, 25mm Size 06, 6-pack
62254	Reamer, 30mm Size 06, 6-pack

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Signature Manifest

Document Number: DC-CETF-000147 **Revision:** Rev. 2
Title: DoC_EU_Hand Files_ Endo-007

All dates and times are in Pacific Standard Time.

Hand Files DoC's MC Approval

01. Modify Approvers for Step (02.Approve)

Name/Signature	Title	Date	Meaning/Reason
Gerry Lara (GERARDO.LARA)	SPECIALIST	13 Jul 2021, 10:01:04 AM	Reviewed

02. Approve

Name/Signature	Title	Date	Meaning/Reason
Mark Dzendzel (MARK.DZENDZEL)	DIRECTOR	13 Jul 2021, 01:22:34 PM	Approved

03. Release

Name/Signature	Title	Date	Meaning/Reason
Gerry Lara (GERARDO.LARA)	SPECIALIST	13 Jul 2021, 01:41:41 PM	Approved

04. Distribution/Notification

Name/Signature	Title	Date	Meaning/Reason
Gerry Lara (GERARDO.LARA)	SPECIALIST	13 Jul 2021, 01:41:41 PM	Email Sent
Mark Anderson (MARK.ANDERSON)		13 Jul 2021, 01:41:41 PM	Email Sent

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Kerr

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Annex VII EC Declaration of Conformity

Manufacturer Name and Address:	Kerr Corporation also trading as Pentrol Clinical 1717 West Collins Avenue Orange, California 92867 USA
Authorized Representative Name and Address:	Kerr Italia S.r.l., Via Passanti 174, 84018 Scafati (SA), Italy
Technical File Name/Number:	Hand Plugger Endo-009
Product Tradename(s):	Buchanan Hand Pluggers
Device Identification:	see Attached list for multiple products
Classification and Rule(s):	Class I, Rule 6
Notified Body:	N/A
Notified Body Number:	N/A
Conformity Assessment Procedure & Certificate Issued:	Annex VII CE Certificate N/A

Declaration Statement:
We hereby declare that the above-mentioned device(s) comply with Council Directive 93/42/EEC.

Regulatory Affairs Signature:

02 July 2021
Issue date

Name: Mark Dzendzel

Title: Director, Quality Assurance Systems

INFOCARD# DC-CETF-000158 - REVISION Rev. 2 , RELEASED ON 06 Jul 2021, STORED AT DC-CE TECH FILE-REL

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Annex VII EC Declaration of Conformity

Hand Plugger / Endo-009	
REF	**Description**
974-0058	Buchanan Hand Plugger 1
974-0059	Buchanan Hand Plugger 2
974-0060	Buchanan Hand Plugger 0

INFOCARD# DC-CETF-000158 - REVISION Rev. 2 , RELEASED ON 06 Jul 2021, STORED AT DC-CE TECH FILE-REL

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Signature Manifest

Document Number: DC-CETF-000158 **Revision:** Rev. 2
Title: Endo-009 Hand Plugger - EU MDD DoC Part 1

All dates and times are in Pacific Standard Time.

Hand Plugger DoC's EU & AU

01. Modify Approvers for Step (02.Approve)

Name/Signature	Title	Date	Meaning/Reason
Gerry Lara (GERARDO.LARA)	SPECIALIST	06 Jul 2021, 08:16:50 AM	Reviewed

02. Approve

Name/Signature	Title	Date	Meaning/Reason
Mark Dzendzel (MARK.DZENDZEL)	DIRECTOR	06 Jul 2021, 09:46:35 AM	Approved

03. Release

Name/Signature	Title	Date	Meaning/Reason
Gerry Lara (GERARDO.LARA)	SPECIALIST	06 Jul 2021, 11:11:54 AM	Approved

04. Distribution/Notification

Name/Signature	Title	Date	Meaning/Reason
Gerry Lara (GERARDO.LARA)	SPECIALIST	06 Jul 2021, 11:11:54 AM	Email Sent
Mark Anderson (MARK.ANDERSON)		06 Jul 2021, 11:11:54 AM	Email Sent

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Attachment C – MDR Quality Management System Certificate - Kerr Italia S.r.l.

Kerr

bsi.

By Royal Charter

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 783335 R000

Manufacturer: Kerr Italia S.r.l.

Address:
Via Passanti, 174
Scafati (SA)
84018
Italy

Single Registration Number: IT-MF-000007768

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2024-01-10**

Current Issue Date: **2024-01-10**

Starting Validity Date: **2024-01-10**

Expiry Date: **2029-01-09**

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Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 783335 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile and non-sterile dental and endodontic instruments	Class IIa
Implantable dental materials	Class IIa, implantable
Non-sterile reusable endodontic instruments	Class Ir
For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

First Issue Date: **2024-01-10**

Current Issue Date: **2024-01-10**

Starting Validity Date: **2024-01-10**

Expiry Date: **2029-01-09**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 783335 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3817666	Issued

First Issue Date: **2024-01-10**

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