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Annex IV EU 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
Single Registration Number (SRN):	
Technical File Name/Number:	Project DUX120 & Technical File R043
Basic UDI-DI:	0841396110000129H
Product Tradename(s):	GingiKNIT+, GingiBRAID+, and GingiBRAID+ with ShortCut Non-Impregnated Retraction Cords
Device Identification:	See Attachment 1
Classification and Rule(s):	I per Annex VIII, Rule 5
Common Standards:	N/A
Notified Body:	N/A
Notified Body Number:	N/A
Conformity Assessment Procedure & Certificate issued:	Annex IV N/A

Declaration Statement:
This declaration of conformity is issued under the sole responsibility of Kerr Corporation. We hereby declare that the above-mentioned device(s) comply with EU MDR 2017/745.

Signed for and on behalf of Manufacturer: Kerr Coporation

Brea, CA — Place

May 24, 2022 — Date of Issue

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

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Non-Impregnated Retraction Cords – Attachment 1
to Annex IV EU Declaration of Conformity

REF	Description
GingiBRAID+	
13214	GingiBRAID+ 1n Non-Impregnated
13215	GingiBRAID+ 2n Non-Impregnated
13216	GingiBRAID+ 3n Non-Impregnated
13217	GingiBRAID+ 0n Non-Impregnated
GingiBRAID+ with ShortCut	
13740	GingiBRAID+ with ShortCut 0n Non-Impregnated
13741	GingiBRAID+ with ShortCut 1n Non-Impregnated
13742	GingiBRAID+ with ShortCut 2n Non-Impregnated
GingiKNIT+	
13498	GingiKNIT+ 000n Non-Impregnated
13499	GingiKNIT+ 00n Non-Impregnated
13500	GingiKNIT+ 0n Non-Impregnated
13501	GingiKNIT+ 1n Non-Impregnated
13502	GingiKNIT+ 2n Non-Impregnated

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MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

PRODUCTION QUALITY ASSURANCE PROCEDURES

This is a declaration made under **Clause 6.6** of **Schedule 3** to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer Name:	Kerr Corporation
Business Address:	1717 West Collins Avenue, Orange, CA 92867, USA
Medical Device(s):	Non-Impregnated Retraction Cord
Classification:	Class I
GMDN Code and Term:	35861 – Retraction cord, gingival
Scope of Application:	All lots

Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and these procedures.

Production Quality Assurance Procedures Certificate:
N/A

Standards Applied:

• EN ISO 1641:2009	Dentistry - Medical devices for dentistry - Materials
• EN ISO 13485:2016	Medical Devices - Quality management systems
• EN 1041:2008+A1 2013	Information supplied by the manufacturer of medical devices
• ISO 8601-1:2019	Date and time – Representations for Information interchange – Part 1: Basic rules
• EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1: General requirements
• EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing
• ISO 10993-2:2006	Biological evaluation of medical devices - Part 2: Animal welfare requirements
• EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

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• EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
• EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
• ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
• MEDDEV 2.7/1 Rev4	Clinical Evaluation: A Guide For Manufacturers And Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
• EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
• IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
• ASTM D4169:2016	Standard Practice for Performance Testing of Shipping Containers and Systems

Authorised Signatory:

May 24, 2022
Issue date

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

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Schedule for 35861 – Retraction cord, gingival

REF	Description
GingiBRAID+	
13214	GingiBRAID+ 1n Non-Impregnated
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13217	GingiBRAID+ 0n Non-Impregnated
GingiBRAID+ with ShortCut	
13740	GingiBRAID+ with ShortCut 0n Non-Impregnated
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