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Annex IV EU Declaration of Conformity

Manufacturer Name and Address:	Kerr Italia S.r.l Via Passanti, 174 Scafati (SA) 84018, Italy
Authorized Representative Name and Address:	N/A
Single Registration Number (SRN):	IT-MF-000007768
Technical File Name/Number:	Occlubrush and OptiShine / R105
Basic UDI-DI:	See Attachment 1
Product Tradename(s):	Occlubrush, OptiShine
Device Identification:	See Attachment 1
Classification and Rule(s):	Class IIa, Rule 5
Intended Purpose:	Polishing of dental restorations
Notified Body:	BSI
Notified Body Number:	2797
Conformity Assessment Procedure & Certificate issued:	Annex XI Part A – Production Quality Assurance EU Quality Assurance Certificate: MDR 783335
Applicable Standards:	See Attachment 2

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

Signed for and on behalf of Manufacturer: Kerr Italia S.r.l.

Scafati, Italy	06-Aug-2025 | 00:48 JST	DocuSigned by: Annabella Del Pozzo 652DDD4BAE86418...
Place	Date of Issue	Name: Annabella Del Pozzo Title: Sr. Manager, RAQA & EHS

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Occlubrush and OptiShine – Technical File R105 Attachment 1 to Annex IV EU Declaration of Conformity		
REF	**Description**	**Basic UDI-DI**
2503	OCCLUBRUSH, REGULAR CUP, 3 PCS	80515118710000685S
2504	OCCLUBRUSH, SMALL CUP, 3 PCS	80515118710000685S
2505	OCCLUBRUSH, POINT, 3 PCS	80515118710000685S
2510	OCCLUBRUSH, REGULAR CUP, 10 PCS	80515118710000685S
2511	OCCLUBRUSH, SMALL CUP, 10 PCS	80515118710000685S
2512	OCCLUBRUSH, POINT, 10 PCS	80515118710000685S
2513	OPTISHINE, 3 PCS	80515118710000685S
2514	OPTISHINE, 10 PCS	80515118710000685S
2520	OCCLUBRUSH ASSORTED KIT	80515118710000685S

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Occlubrush and OptiShine – Applicable Standards Attachment 2 to Annex IV EU Declaration of Conformity	
Standard	**Title**
EN ISO 13485:2016, EN ISO 13485:2016 /AC:2018 EN ISO 13485:2016/A11:2021 (ISO 13485:2016)	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019, EN ISO 14971:2019/A11:2021 (ISO 14971:2019)	Medical devices – Application of risk management to medical devices
EN ISO 7405:2018 (ISO 7405:2018)	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 10993-1:2020 (ISO 10993-1:2018)	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-2:2022 (ISO 10993-2:2022)	Biological evaluation of medical devices – Part 2: Animal welfare requirements
EN ISO 10993-5:2009 (ISO 10993-5:2009)	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2023 (ISO 10993-10:2021)	Biological evaluation of medical devices – Part 10: Tests for skin sensitization
EN ISO 10993-12:2021 (ISO 10993-12:2021)	Biological evaluation of medical devices – Part 12: Sample preparation and reference
EN ISO 10993-23:2021 (ISO 10993-23:2021)	Biological evaluation of medical devices – Part 23: Tests for irritation
EN ISO 20417:2021 (ISO 20417:2021)	Medical Devices – Information to be supplied by the manufacturer (ISO 20417:2021)
EN ISO 15223-1:2021 (ISO 15223-1:2021)	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1: General requirements
EN ISO 9687:2015+A1:2018 (ISO 9687:2015)	Dentistry – Graphical symbols for dental equipment
ISO 8601-1:2019	Date and time – Representations for Information interchange – Part 1: Basic rules
EN 62366-1:2015+A1:2020 (IEC 62366-1:2015)	Medical devices – Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015)
EN ISO 17665:2024 (ISO 17665:2024)	Sterilization of health care products. Moist heat. Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 17664-1:2021 (ISO 17664-1:2021)	Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices, Part 1: Critical and semi-critical medical devices
EN 1639:2009	Dentistry – Medical devices for dentistry – Instruments
EN ISO 1797:2017 (ISO 1797:2017)	Dentistry – Shanks for rotary and oscillating instruments
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems

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Occlubrush and OptiShine – Applicable Standards Attachment 2 to Annex IV EU Declaration of Conformity	
Standard	**Title**
ISTA 2A:2011	Partial Simulation Performance Test for Packaged Products 150 lbs or Less
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices
MDCG 2020-13	Clinical evaluation assessment report template
MEDDEV 2.7/1 Rev. 4	Guideline on Medical Devices Clinical Evaluation
MEDDEV 2.12/1 Rev. 8	Guidance document – Market surveillance – Guidelines on a Medical Devices Vigilance System
MEDDEV 2.12/2 Rev. 2	Post Market Clinical Follow-up Studies

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INFOCARD# DC-CETF-000765 - REVISION Rev0 , RELEASED ON 07 Aug 2025, STORED AT DC-CE TECH FILE-REL

Signature Manifest

Document Number: DC-CETF-000765 **Revision:** Rev0
Title: Occlubrush and OptiShine EU MDR DOC
Effective Date: 07 Aug 2025

All dates and times are in Pacific Standard Time.

Occlubrush and OptiShine EU MDR DOC

01. Modify Approvers for Step (02.Approve)

Name/Signature	Title	Date	Meaning/Reason
Michael Haider (MICHAEL.HAIDER)	ASSOCIATE RA	07 Aug 2025, 02:37:06 PM	Reviewed

02. Approve

Name/Signature	Title	Date	Meaning/Reason
Michael Haider (MICHAEL.HAIDER)	ASSOCIATE RA	07 Aug 2025, 02:37:40 PM	Approved

03. Release

Name/Signature	Title	Date	Meaning/Reason
Michael Haider (MICHAEL.HAIDER)	ASSOCIATE RA	07 Aug 2025, 02:38:12 PM	Approved

04. Distribution/Notification

Name/Signature	Title	Date	Meaning/Reason
Annabella Del Pozzo (ANNABELLA.DELPOZZO)	RA/QA Sr. Manager	07 Aug 2025, 02:38:13 PM	Email Sent
Jeannie Back (JEANNIE.BACK)	SUPERVISOR, QA AND RA	07 Aug 2025, 02:38:13 PM	Email Sent
Jennifer Conyers (JENN.CONYERS)	Manager, Regulatory Affairs	07 Aug 2025, 02:38:13 PM	Email Sent
Jennifer Evans (JENNIFER.EVANS)	VP RA/QA Consumable	07 Aug 2025, 02:38:13 PM	Email Sent
Brian Wong (BRIAN.WONG)	Program Manager	07 Aug 2025, 02:38:13 PM	Email Sent
Michael Haider (MICHAEL.HAIDER)	ASSOCIATE RA	07 Aug 2025, 02:38:13 PM	Email Sent
Ryan Bermudez (RYAN.BERMUDEZ)		07 Aug 2025, 02:38:13 PM	Email Sent
Mark Anderson (MARK.ANDERSON)		07 Aug 2025, 02:38:13 PM	Email Sent

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