EG - KOFORMITÄTSERKLÄRUNG
EC-DECLARATION OF CONFORMITY

(nach dem Anhang IV der EG-Richtlinie (EU) 2017/745)
(in accordance with Annex IV of Medical Device Regulation (EU) 2017/745)

Hersteller /Company :	**DoriDent Dr.Hirschberg GmbH**
Adresse /address	**Mollardgasse 85a, A-1060 Wien, Austria**
SRN:	**AT-MF-000039190**

We herewith declare under our sole responsibility that the following Class I Products (rule 5)
According to Annex VIII of the MDR

GENERIC NAME **ARTICULATING PAPER**

TRADE NAME ARTICULATING PAPER
(12 x 10) straight, blue/blue, 40 micron
(12 x 10) straight, red/blue, 40 micron
(12 x 10) straight, red/blue, 80 micron
(6 x 10) horse-shoe form, red/blue, 40 micron
(6 x 10) horse-shoe form, red/blue, 80 micron

GMDN	**16181**
EMDN	**Q01020201**
BASIC UDI-DI	**9120134391887R**

comply with general safety and performance requirements of the Medical Device Regulation (EU) 2017/745
Harmonized and other Standards:
EN ISO 13485:2021 - Medical devices – Quality Management Systems - Requirement for regulatory purpose
EN ISO 14971:2019/A11:2021 Medical devices Application of risk management to medical devices
EN ISO 10993-1:2020 - Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
EN ISO 7405:2018 – Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 10993-18:2020 - Biological evaluation of medical devices - Part 18: Chemical characterization of materials
ISO/TS 10993-19:2020 - Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials
EN 62366-1:2015/A1:2020 - Medical devices - Part 1: Application of usability engineering to medical devices
ISO/TR 20416:2020 - Medical devices - Postmarket surveillance for manufacturers
EN ISO 20417:2021 - Information supplied by the manufacturer of medical devices
EN 1641:2009 - Dentistry – Part 1: Medical device for dentistry - Materials
EN ISO 15223-1:2021 – Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied – Part I: General requirements

The validity of the declaration of conformity is linked to a change in the medical device

Vienna 23.01.2024
Place, Date

Dr. Doris Hirschberg
Responsible person for MD and technical files

Signature :

DoriDent
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