EC Declaration of Conformity

Report No :ADK-T-02-12(Rev.16)

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Date :Dec 13 ,2021

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EC Declaration of Conformity

In accordance with EC directives 93/42/EEC and 2017/745/EC relating to Medical Devices.

We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the requirements of the above EC Directive.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid.

Product :

1) Dental Absorbent Point

2) Dental Root-Canal Obturating Points

Model Name :

1) Sterile Absorbent Paper Points (Class IIa)

2) Gutta Percha Points (Class IIa)

Relevant EC Directives :*Medical Device Directive 93/42/EEC and* 2017/745/EC

Applied standard:

- Council Directive 93/42/EEC and 2017/745/EC

- EN ISO 14971 [2012] Medical devices Application of risk management to medical devices

- EN ISO 1041 [2008] Information supplied by the manufacturer with medical devices

- EN ISO 980 [2008] Graphical symbols for use in the labeling of medical devices

- ISO 9001[2008] Quality systems - Model for quality assurance in design, development, production, installation and servicing

- EN ISO 15223-1:[2016] Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

- ISO 6877 [2006] Dentistry - Root-canal obturating points

- ADA - ANSI/ADA Specification no. 57 for Endodontic Filling Materials

- EN 1641 [2009] Dentistry - Medical devices for dentistry - Materials

- ISO 7551 [1996] Dental absorbent points

- EN 556-1 [2001] Sterilization of Medical Device- Requirements for terminally- Sterilized devices to be labelled "Sterile"

- EN 1641 [2009] Dentistry - Medical devices for dentistry – Materials

- EN ISO 10993-1 [2018] Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

- ISO 11137 [2006] Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

- MEDDEV 2.7.1 REV.4 GUIDELINES ON MEDICAL DEVICE

- ISO13485[2016] Medical devices —Qualitymanagement systems —Requirements for regulatory purposes

Representative harmonised standard (eg. ISO6877, ADA)

is subject to the procedure set out in Annex 5 of Directive 93/42/EEC under the supervision of Notified Body Number 1639, SGSBelgium NV, SGS House Noorderlaan 87 2030 Antwerp Belgium

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