EC Certificate Full Quality Assurance System: Certificate KR19/81826259

The management system of

META BIOMED CO., LTD.

(Head office & Osong Factory) 270, Osongsaengmyeong1-ro, Osong-eup,
Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 25 August 2020 until 05 March 2024
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 03 April 2003
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/PCI 208838

Authorised by

SGS Belgium NV, Notified Body 1639
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META BIOMED CO., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 3

Detailed scope

Sterile Absorbent Paper Points;
Dental Root-Canal Obturating Materials (Gutta Percha Points and Bars, Gutta Percha Bar Plus, Gutta Percha Points-S);
Calcium Hydroxide Temporary Filling Material (Metapaste);
Hydraulic Temporary Restorative Material (MD-Temp, MD-Temp Plus);
Resin Based Root Canal Sealer (ADSEAL, ADSEAL Plus);
Bioceramic root canal sealer (CeraSeal);
Silicone-based endodontic sealer (GuttaSil);
Root Canal Cleaning and Smear Layer Removing Solution (MD-Cleanser, MD-ChelCream);
Warmed Gutta Percha Obturation System including Gun, Pen, Gun Needle and Pen Tip (E & Q Master, GENESYS Pack and Fill, elementsfree);
Dental Temporary Cement (NETC);
Dental Etchant (Meta Etchant);
Dental Resin Cement (Metacem);
Dental adhesive (Meta P&Bond);
Dental Composite Resin (Nexcomp, Nexcomp Flow, NexCore, Ezfil);
Dental Light Curing Cavity Liner (Biner LC);
Light cured temporary filling materials (NexTemp LC, NexTemp HV);
Glass fiber reinforced composite root post system including post, post drill (NexPost);
Reusable Rotary Endo File for root canal cleaning and shaping (Aurum).

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

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