

EC Certificate Full Quality Assurance System: KR03/58773

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 27 June 2018 until 06 February 2023
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 06 February 2021

Issue 51. Certified since 03 April 2003

Certification is based on reports numbered WW/PCI/208838

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by



SGS United Kingdom Ltd, Notified Body 0120

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EC Certificate Full Quality Assurance System: KR03/58773, continued

META BIOMED CO., LTD.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 51

Detailed scope

Sterile Absorbent Paper Points;
Dental Root-Canal Obturating Materials (Gutta Percha Points and Bars, Gutta Percha Plus, Gutta Percha Bar Plus);
Calcium Hydroxide Temporary Filling Material (Metapaste);
Hydraulic Temporary Restorative Material (MD-Temp, MD-Temp Plus);
Resin Based Root Canal Sealer (ADSEAL);
Zinc Oxide Based Root Canal Sealer (ZOB Seal);
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);
Dental Light Curing Cavity Liner (Biner LC);
Light cured temporary filling materials (NexTemp LC, NexTemp HV);
Sterile non-absorbable polymer ligating clip for vessel or tissue ligation (Meta Clip);
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

Additional facilities

(Cheongju Factory) 136, Mochung-ro, Seowon-gu, Cheongju-si, Chungcheongbuk-do, Korea