

Certificate Number KR19/81826153

The management system of

META BIOMED CO., LTD.

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

Dun & Bradstreet D-U-N-S identification number : 68-832-2841

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009

Canada:
Medical Devices Regulations – Part 1 SOR 98/282

Japan:
MHLW Ministerial Ordinance 169 /Article 4 to Article 68 / PMD Act

United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2020-11-16 until Expiry Date: 2022-08-07
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2022-01-18
Issue 4. Certified since 2019-08-08

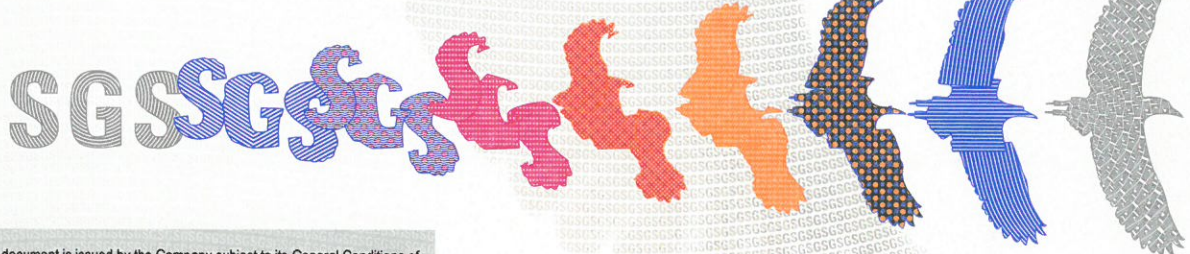
Authorised by J Hall
Business Manager



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MDSAP M2

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The management system of

META BIOMED CO., LTD. MDSAP (ISO 13485:2016)

Issue 4

Detailed scope

Design and manufacture of Sterile Absorbent Paper Points, Dental Root-Canal Obturating Materials, Temporary Filling Materials, Hydraulic Temporary Restorative Material, Dental Composite Resin, Dental Temporary Cement, Dental Cleanser, Dental Root Canal Sealer, Dental Etchant, Dental Resin Cement, Dental adhesive, Dental Light Curing Cavity Liner, Warmed Gutta Percha Obturation System, Sterile Bone Void Fillers, Root Post System including post and post drill and Reusable Rotary Endo File for the area of dentistry.

