META BIOMED CO., LTD.
Osong factory): 270, Osongsaengmyeong1-ro, Osong-eup,
Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea
T) +82-43-216-0433 F) +82-43-217-1988
Email: info@meta-biomed.com Home Page: www.meta-biomed.com

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

For the following medical device :

Product Name :	EDTA Cream for Root Canal Cleaning and Smear Layer Removal
Brand Name :	MD – ChelCream
Classification :	Class IIa by Rule 6 of Annex IX, Council Directive 93/42/EEC as amended by Directive 2007/47/EC
Manufacturer's Name :	META BIOMED CO., LTD.
Manufacturer's Address :	270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea

is herewith the conformity with the requirements set out in the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 concerning Medical Devices declared, For the evaluation of the conformity with this Directive, the following standards have been applied:

EN ISO 13485:2016, MEDDEV 2.12-1 Rev.8, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12.2 Rev.2, Directive 93/42/EEC amended by Directive 2007/47/EC, EN ISO 14971:2012, EN 1041:2008, EN ISO 15223-1:2016, EN 1641:2009, EN ISO 6876:2012, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 7405:2018, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2019, EN ISO 14644-4:2001, EN ISO 14644-5:2004, KS I ISO14644-6:2017, EN ISO 14644-7:2004,EN ISO 14644-8:2013 ISTA 1A:2016

is subject to the procedure set out in Annex II (excluding section 4) of Directive 93/42/EEC under the supervision of Notified Body Number 1639, SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium.

GMDN Code : 45500(Root canal cleansing solution)

EC Certificate Number : KR19/81826259

Responsible for making this declaration is the :

■ Manufacturer: META BIOMED CO., LTD.

European Representative is:

■ Meta Biomed Europe GmbH, Wiesenstr. 35, 45473 Mülheim an der Ruhr, Germany

■ Tel:+49-208-30991910, Fax: +49-208-30991999

We, the manufacturer's declaration, declare and ensure with sole responsibility, that the Medical Device meet the provisions of Council Directive 93/42/EEC(Medical Device Directive) which apply to them

Person responsible for making this declaration:

Name, Surname : **Suk Song Oh**

Position/Title : **PRESIDENT**

Suk Song Oh

Place: Cheongju-si **Date:** February 2nd, 2021

(Company stamp and legal signature)

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(Attachment: Model name list)

No	Brand Name	Model Name
1	MD-ChelCream	MD-ChelCream
2		MD-ChelCream 2.5