MEDICLUS CO.,LTD. No. 1210, 134, Gongdan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
TEL +82-43-211-2877 FAX +82-43-211-2866 e-mail : sales@mdclus.com www.mediclus.co.kr

EC Declaration of Conformity

▣ **Manufacturers Registered Name :** ***MEDICLUS CO., LTD***
No. 1210, 134, Gongdan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea

▣ **EC Representative :** ***S.B. PHARMA GMBH***
Max-Planck str. 39a D-50858, Koln, Germany

▣ **Description of Device :** Any-Pex is Calcium hydroxide based root canal filling material. It has excellent properties and biocompatibility complied with requirement of ISO 6876:2012.
This product is the material that recharges the root canal during root canal treatment**.**

1. Product name: Dental root canal filling material
2. Type/Brand name: Any-Pex
3. Model Name: Any-Pex
4. UDI-DI:
5. GMDN code: 40592
6. Classification : *Class IIa (Rule 7)*

The device that is covered by the present declaration is in conformity with this regulation and, if applicable, with any other relevant union legislation that provides for the issuing of an EU declaration of conformity.

Digitally signed by Romanenco Alexandru
Date: 2028.11.21 16:13:10 EET
Reason: MoldSign Signature
Location: Moldova

is in conformity with the national standard transposing harmonized standards :

No.	Category	Name	Description
1	System	Directive 2007/47/EC	5 September 2007 concerning medical devices
		ISO 13485 : 2016	Medical devices - Quality management systems - Requirements for regulatory
		EN ISO 14971 : 2012	Medical devices - Application of risk management to medical devices
		MEDDEV 2.12-1 Rev.8	Guidelines on a medical device vigilance system
2	ETC	MEDDEV 2.4/1 Rev.9	Guidelines relating to the application of the council directive 93/42/EEC on medical devices
		BS EN 1641: 2009	Dentistry. Medical devices for dentistry. Materials
		EN 1041:2008	Information supplied by the manufacturer with medical devices
3	Biological evaluation	ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1 : Evaluation and testing within a risk management process
		ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5 : Tests for in vitro cytotoxicity

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		ISO 10993-10: 2010	Biological evaluation of medical devices - Part 10 : Tests for irritation and delayed-type hypersensitivity
		ISO 10993-11: 2017	Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity
4	Performance	ISO 6876:2012	Dental root canal sealing material
5	Packing	ISTA	Integrity Test Procedure 2A
6	Label	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

◈ The device has not included a substance or human blood derivative.

◈ The device has not included the production tissues of animal origin covered by 2003/32/EC directive in chemical & substance declaration.

Notified Body is subject to the procedure set out in Annex Ⅱ excluding of Directive 93/42/EEC amended by 2007/47/EC under the supervision of Notified Body Number 0068, MTIC, Via Leopardi, 14-20123 MILANO (MI) ITALY.

26,01,2022

MEDICLUS Co., Ltd.

President Lydia Kim of
MEDICLUS CO., LTD

MTIC INTERCERT

CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/312-2021

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. **MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.**

MANUFACTURER: **MEDICLUS CO., LTD.**

No. 1210, 134, Gongdan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, KOREA

DEVICE/S:

- ✓ **Dental root canal sealer**
- ✓ **Dental temporary filling material**
- ✓ **Dental composite resin**
- ✓ **Dental temporary cement**

BRAND NAME/S: *full list of brand names in annex 1*

MODEL/S: *full list of models in annex 1*

FIRST ISSUE: **23/02/2021** CURRENT ISSUE: **07/05/2021** REVISION Nr.: **01** EXPIRING DATE: **27/05/2024**

This certificate is also composed by n. 1 annex made of 1 page.

Dipl.- Ing. Feridoon Sergizzarea
MTIC INTERCERT Certification Body

MTIC INTERCERT S.r.l. - Via Moscova, 11 - 20017 RHO (MI) - ITALY
www.mtic-group.org info@mtic-group.org

CERTIFICATE

ANNEX No. 1 TO THE FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/321-2021

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

DEVICE/S:	BRAND NAME/S:	MODEL/S:
✓ **Dental root canal sealer**	✓ Any-Seal RC	✓ AS10GBX1S
	✓ One-Fil	✓ OS2GBX1S
✓ **Dental temporary filling material**	✓ Once-Fil Flow	✓ OF1GBS5S-B
		✓ OF1GBS5S-Y
	✓ Ezi-Crown	✓ Ezi-Crown LC (A1, A2, A3)
✓ **Dental composite resin**	✓ Any-Core	✓ Any-Core tooth(A3)
		✓ Any-Core white
		✓ Any-Core blue
	✓ Any-Com Flow	✓ Any-Com Flow Kit
		✓ Any-Com Flow Rainbow
		✓ Any-Com Flow Refill (Any-Com Flow A1, Any-Com Flow A2, Any-Com Flow A3, Any-Com Flow A3.5, Any-Com Flow A4, Any-Com Flow B1, Any-Com Flow B2, Any-Com Flow B3, Any-Com Flow C2, Any-Com Flow C3, Any-Com Flow D2, Any-Com Flow OA2, Any-Com Flow OA3, Any-Com Flow TL, Any-Com Flow OWT, Any-Com Flow YTL, Any-Com Flow RTL)
✓ **Dental temporary cement**	✓ Any-Temp	✓ Any-Temp NE

FIRST ISSUE OF THE CERTIFICATE: **23/02/2021** CURRENT ISSUE OF THE CERTIFICATE: **07/05/2021** CERTIFICATE IN REVISION Nr.: **01** EXPIRING DATE OF THE CERTIFICATE: **27/05/2024**

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