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

Digitally signed by Romanenco Alexandru
Date: 2024.10.17 10:24:26 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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/312-2021

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

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

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

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	MEDICLUS CO., LTD.
Manufacturer address and contact details	Address : No. 1210, 134, Gongdan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea Contact : +82-43-904-2877, ra@mdclus.com
Single Registration Number (SRN) (if available)	KR-MF-000022584

Authorised Representative name (if applicable)	KTR Europe GmbH
Authorised Representative address and contact details	Address : Mergenthalerallee 77, 65760 Eschborn, Germany Contact : +49-6196-887170
Single Registration Number (SRN) (if available)	DE-AR-000005685

Notified body name (if applicable)	MTIC INTERCERT S.r.l. □ See attached schedule
Notified body number (if applicable)	CE 0068 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	0068/QCO-DM-312-2021 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	27/05/2024 □ See attached schedule
End date of extended validity/transition period	31/12/2028 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☑ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.

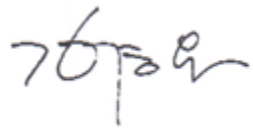
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name MEDICLUS CO., LTD.

Location & Date Korea / August 30, 2024

Signature, Print Name, Title



,Kim Kyoung-Eun, CEO of MEDICLUS CO., LTD

Contact : Sales@mdclus.com

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

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Dental root canal sealer (Any-Seal RC)	**0068/QCO-DM-312-2021, CE 0068 (MTIC)**	**27/05/2024**	**MTIC INTERCERT S.r.l., CE 0068**	**DNV, CE 2460**	**31/12/2028**	
Dental root canal sealer (One-Fil)	**0068/QCO-DM-312-2021 CE 0068 (MTIC)**	**27/05/2024**	**MTIC INTERCERT S.r.l., CE 0068**	**DNV, CE 2460**	**31/12/2028**	
Dental temporary filling material (Once-Fil Flow)	**0068/QCO-DM-312-2021 CE 0068 (MTIC)**	**27/05/2024**	**MTIC INTERCERT S.r.l., CE 0068**	**DNV, CE 2460**	**31/12/2028**	
Dental temporary filling material (Ezi-Crown)	**0068/QCO-DM-312-2021 CE 0068 (MTIC)**	**27/05/2024**	**MTIC INTERCERT S.r.l., CE 0068**	**DNV, CE 2460**	**31/12/2028**	
Dental composite resin (Any-Core)	**0068/QCO-DM-312-2021 CE 0068 (MTIC)**	**27/05/2024**	**MTIC INTERCERT S.r.l., CE 0068**	**DNV, CE 2460**	**31/12/2028**	
Dental composite resin (Any-Com Flow)	**0068/QCO-DM-312-2021 CE 0068**	**27/05/2024**	**MTIC INTERCERT S.r.l., CE 0068**	**DNV, CE 2460**	**31/12/2028**	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

	(MTIC)					
Dental temporary cement (Any-Temp)	**0068/QCO-DM-312-2021 CE 0068 (MTIC)**	**27/05/2024**	**MTIC INTERCERT S.r.l., CE 0068**	**DNV, CE 2460**	**31/12/2028**	

Notified Body Confirmation Letter Reference: C682954

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MEDICLUS CO., LTD.
No. 1210, 134, Gongdan-ro, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea

SRN Number (if available): KR-MF-000022584

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.

Place and date:
Høvik,2024/09/24

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Rajesh Kumar Chellappan
Management Representative

- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Bioceramic Root Canal Sealer (One-Fil) / Basic UDI DI: 880951834EN03JV	IIa	Dental root canal sealer (One-Fil) (Name change only)	0068/QCO-DM-312-2021, MTIC (CE 0068)
Dental Temporary Filling Material (Once-Fil Flow) / Basic UDI DI: 880951834TP02NE	IIa	N/A	0068/QCO-DM-312-2021, MTIC (CE 0068)
Any-Com Flow Dental Restoration Procedure Pack (Any-Com Flow) / Basic UDI DI: 880951834RS03NH	IIa	Dental Composite Resin (Any-Com Flow) (Name change only)	0068/QCO-DM-312-2021, MTIC (CE 0068)
Light Cured Temporary Crown and Bridge Resin (Ezi-Crown) / Basic UDI DI: 880951834TP05NL	IIa	Dental temporary filling material (Ezi-Crown) (Name change only)	0068/QCO-DM-312-2021, MTIC (CE 0068)
Dental Temporary Cement (Any-Temp NE) / Basic UDI DI: 880951834TP03NG	IIa	Dental Temporary Cement (Any-Temp) (Name change only)	0068/QCO-DM-312-2021, MTIC (CE 0068)
Dual Cured Dental Composite Resin (Any-Core) / Basic UDI DI: 880951834RS02NF	IIa	Dental composite resin (Any-Core) (Name change only)	0068/QCO-DM-312-2021, MTIC (CE 0068)
Resin-based Root Canal Sealer (Any-Seal RC) / Basic UDI DI: 880951834EN05JZ	IIa	Dental root canal sealer (Any-Seal RC) (Name change only)	0068/QCO-DM-312-2021, MTIC (CE 0068)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/09/24	C682954	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.