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BioSCIENCE GmbH · Walsmühler Straße 18 · 19073 Dümmer

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	BioScience GmbH
Manufacturer address and contact details	Walsmühler Straße 18 19073 Dümmer, Germany
Single Registration Number (SRN) (if available)	DE-MF-000004925

Notified body name (if applicable)	x See attached schedule
Notified body number (if applicable)	x See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	x See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	x See attached schedule
End date of extended validity/transition period	x 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.

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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 Certificates covering the listed devices

- were issued after 25 May 2017
- were valid on 26 May 2021 and have not been withdrawn afterwards
- expire *after* 20 March 2023.

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.

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

Devices as listed in the attached schedule

- continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- 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	BioScience GmbH
Location & Date	Dümmer/Germany, 01.03.2024
Signature, Print Name, Title	Michelle Rahn, CEO
Contact Details (at least email)	m.rahn@biopolymer.info

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BioScience GmbH
Walsmühler Straße 18
19073 Dümmer, Germany

[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

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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)
Hyadent BG, BS091	**CE 641036 CE 642222**	**26.05.2024**	**BSI, 2797**	**CE Certiso Ltd., 2409**	**31.12.2027**	**n/a**
Hyacorp Endogel, BS080	**CE 641036 CE 641232**	**26.05.2024**	**BSI, 2797**	**CE Certiso Ltd., 2409**	**31.12.2027**	**n/a**

[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)

CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. – NB 2409
H-2092 Budakeszi, Erdő utca 101.

12-03-2024

Notified Body Confirmation Letter

Reference: K-2024/35

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, CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2409 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:

BioScience GmbH
Walsmühler Straße 18,
D-19073 Dümmer
Germany

SRN Number (if available): DE-MF-000004925

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 90/385/EEC (AIMDD) or 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/AIMDD certificate expiry; or provided

CE Certiso Kft.
H-2092 Budakeszi, Erdő u. 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

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
- 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)

On behalf of the Notified Body,

signed by: Dr. Valter Papp
CE Certiso KFT.

Valter PAPP, dr.

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 or 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/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Hylan solution - Non-modified (non-cross-linked) hyaluronic acid gel	Class III	N/A	Certificate No. **144983-20-05-19**; NB2409 Certificate No. **144984-20-05-19**; NB2409
Hylan Gel Dermal - Cross-linked hyaluronic acid gel	Class III	N/A	Certificate No. **144983-20-05-19**; NB2409 Certificate No. **144985-20-05-19**; NB2409

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Device name or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Hylan Gel Contour - Cross-linked hyaluronic acid gel	Class III	N/A	Certificate No. **144983-20-05-19**; NB2409 Certificate No. **144986-20-05-19**; NB2409
Hylan Gel Dermal Filler DX - Cross-linked hyaluronic acid with dextranomer	Class III	N/A	Certificate No. **144983-20-05-19**; NB2409 Certificate No. **144987-20-05-19**; NB2409
HyaProf Hylan Gel Dermal Cohesive Filler - Cross-linked cohesive hyaluronic acid	Class III	N/A	Certificate No. **144983-20-05-19**; NB2409 Certificate No. **144988-20-05-19**; NB2409
Hyadent BG - Implantable prosthetic and osteosynthesis devices – various	Class III	N/A	Certificate No. **CE 641036**, NB2797 Certificate No. **CE 642222**, NB2797 incl. Rev.
Hyacorp endogel - Dressings for the prevention of post-operative adhesions	Class III	N/A	Certificate No. **CE 641036**, NB2797 Certificate No. **CE 642232**, NB2797 incl. Rev.

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 or 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	*N/A*

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Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
12-03-2024	K-2024/35	Initial issue

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