Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- 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	Boditech Med Inc,.
Manufacturer address and contact details	43, Geodudanji 1-gil, Dongnae-myeon, Chuncheon-si, Gang-won-do 24398, Republic of Korea Tel: +82(0) 33 243 1435
Single Registration Number (SRN) (if available)	KR-MF-000011028

Authorised Representative name (if applicable)	Obelis S.A.
Authorised Representative address and contact details	Bd. Général Wahis 53, 1030 Brussels, Belgium
Single Registration Number (SRN) (if available)	BE-AR-000000106

Notified body name (if applicable)	☒ See attached schedule ☐ Not applicable
Notified body number (if applicable)	☒ See attached schedule ☐ Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule ☐ Not applicable
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	☒ See attached schedule ☐ Not applicable
End date of extended validity/transition period	☒ See attached schedule

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We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR 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 IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 May 2025 for class D devices

☒ 26 May 2026 for class C devices

☒ 27 May 2027 for class B and class A (sterile) devices

☐ Signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 September 2025 for class D devices

☐ 26 September 2026 for class C devices

☐ 27 September 2027 for class B and class A (sterile) devices

☐ We do not intend to lodge an application for conformity for the device as indicated on the attached schedule.

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

- Directive Certificate(s) covering the device(s) listed in the attached schedule was/were issued after 25 May 2017, was/were valid on 26 May 2022 and has/have not been withdrawn afterwards.

Choose applicable statements:

☐ Original expiry date *before 9 July 2024*:

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☐ 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 IVDR for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of its/their substitute(s), or

☐ Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54(1) IVDR (may be provided upon request), or

☐ Competent Authority has required us as the manufacturer, in accordance with Article 92(1) IVDR, 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 54(1) or a requirement per Article 92(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 IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 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 IVDR before 26 September 2025.

☐ We do not intend to lodge an application for conformity assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

☒ Original expiry date *after 9 July 2024*:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 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 IVDR before 26 September 2025.

☐ We do not intend to lodge an application for conformity assessment by 26 May 2025 for the devices as indicated on the attached schedule, therefore the transition period will end on 26 May 2025.

☐ assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.
☐ QMS in accordance with Article 10(8) IVDR is in place.

☒ Notified body has issued the attached certificate for the IVDR-compliant QMS.

➢ **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

- The device(s) continue(s) to comply with the IVDD.
- 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.

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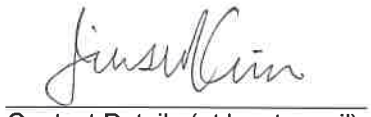
Signed for and on behalf of the manufacturer:

Full Company Name: Boditech Med Inc.

Location & Date: Republic of Korea, October 27, 2025

Signature, Print Name, Title: Jinsu Kim, PRRC



Contact Details (at least email): kjs3@boditech.co.kr

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Schedule of Devices

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

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)		**End date of extended validity / transition period**	**Notified Body name and number where the IVDR application was lodged/contract signed** (if applicable)
SMFP-75	AFIAS Infliximab	2028.12.31	TUV SUD, 0123
SMFP-118	AFIAS Adalimumab	2028.12.31	TUV SUD, 0123
SMFP-91	AFIAS Golimumab	2028.12.31	TUV SUD, 0123
SMFP-115	AFIAS Vedolizumab	2028.12.31	TUV SUD, 0123
SMFP-114	AFIAS Ustekinumab	2029.12.31	TUV SUD, 0123
SMFP-93	AFIAS Etanercept	2028.12.31	TUV SUD, 0123
SMFP-110	AFIAS Rituximab	2028.12.31	TUV SUD, 0123
SMFP-86	AFIAS Free Anti-Infliximab	2028.12.31	TUV SUD, 0123
SMFP-76	AFIAS Total Anti-Infliximab	2028.12.31	TUV SUD, 0123
SMFP-137	AFIAS Free Anti-Adalimumab	2028.12.31	TUV SUD, 0123
SMFP-90	AFIAS Free Anti-Golimumab	2028.12.31	TUV SUD, 0123
SMFP-100	AFIAS Free Anti-Vedolizumab	2028.12.31	TUV SUD, 0123
SMFP-101	AFIAS Free Anti-Ustekinumab	2028.12.31	TUV SUD, 0123
SMFP-92	AFIAS Free Anti-Etanercept	2028.12.31	TUV SUD, 0123
SMFP-97	AFIAS Free Anti-Rituximab	2028.12.31	TUV SUD, 0123
SMFP-99	AFIAS IGRA-TB	2028.12.31	TUV SUD, 0123

[1] for devices with IVDD 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

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