Manufacturer's Declaration

TECHNOLOGIE MEDICALE'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, in particular with respect to

- the validity of certificates issued under 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	TECHNOLOGIE MEDICALE
Manufacturer address and contact details	Address: 101 rue Vaillant Couturier, 93130 Noisy le sec, FRANCE Phone number : +33 (0)1 48 45 58 95 E-mail : info@technologiemedicale.com
Single Registration Number (SRN) (if available)	FR-MF-000000498

Authorised Representative name (if applicable)	Non applicable
Authorised Representative address and contact details	Non applicable
Single Registration Number (SRN) (if available)	Non applicable

Notified body name (if applicable)	GMED/Groupe LNE See attached schedule
Notified body number (if applicable)	0459 See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	28577 rev. 8 See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	May 26th, 2024 (included) See attached schedule
End date of extended validity/transition period	December 31, 2028 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.

Manufacturer's Declaration

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** 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 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.

[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

☒ 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.

Manufacturer's Declaration

Signed for and on behalf of the manufacturer:

TECHNOLOGIE MEDICALE

Noisy-le-Sec, May 13th 2024

Alexandre ITZKOWITCH, CEO

Tel : + 33 (0)1.48.45.28.01
Email : a.itzkowitch@technologiemedicale.com

Manufacturer's Declaration

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)
Debflo 366616612DEBFBV	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Debplus 366616612DEBPCH	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Debson TM2 366616612DEBSCP	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
RTM3 366616611RTM3GU	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Dédoubleur 366616650DRALD	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Rampe 366616650DRALD	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Flexible 366616640FLEL2	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Humidificateur 366616616HUMMY	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
SWITCH 366616619FSWNR	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
FLOW-SWITCH 366616619FSWNR	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable

[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)

TECHNOLOGIE MEDICALE

Manufacturer's Declaration

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)
RVTM3 366616620RVT3HV	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Soupape de Jeanneret 366616620SDJLX	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Vanne de vide 366616620VDVN6	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Vanne de vide Australie 366616620VDVGHB	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Venturi TM2 366616620VTM2HQ	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Minireg 366616613MREGGK	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Regflow TM 366616613DETKM	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Regson TM2 366616613DETKM	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Detreg TM 366616613DETKM	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable
Blender TM2 366616614BTM2EB	28577 rev. 8	May 26th, 2024	GMED, 0459	GMED, 0459	December 31, 2028	Non applicable