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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*
- 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	Unimed Medical Supplies Inc
Manufacturer address and contact details	Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, 518108, Shenzhen, PEOPLE'S REPUBLIC OF CHINA Tel : +8675526695165 Web: www.unimed.cn
Single Registration Number (SRN)	CN-MF-000001480

Authorised Representative name	Obelis s.a.
Authorised Representative address and contact details	Boulevard Général Wahis 53 1030 Brussels, BELGIUM Tel: +(32)2.732.59.54 E-Mail: mail@obelis.net
Single Registration Number (SRN)	BE-AR-000000106

Notified body name	TÜV SÜD Product Service GmbH
Notified body number	0123
Directive Certificate number(s) to which this confirmation is made	G1 0664560022 Rev.00
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	8 June 2023
End date of extended validity/transition period	31 December 2028

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*
- 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,

by complying with the following conditions:

➢ **Directive Certificate(s)**

The directive certificate for the products was issued after September 24, 2019 was valid on 8 June 2023, and has not been revoked there after.

A formal application(s) for conformity assessment to the Notified Body in accordance with the first subparagraph of Section 4.3 of Annex VII of the MDR has been submitted by us by May 26, 2024 for the listed devices and a signed written agreement in accordance with the second subparagraph of Section 4.3 of Annex VII of the MDR is in place prior to September 26, 2024.

➢ **Quality Management System (QMS)**

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

➢ **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:

Unimed Medical Supplies Inc

Bld#8, Nangang 3rd Industrial Park, Tangtou, Shiyan, 518108, Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

2024-09-20

George Hu

General Manager

georgehu@unimed.cn

Sources: Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32023R0607

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Schedule of Devices

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

Identification of the device(s) (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)
SpO2 Sensor	G1 0664560022 Rev.00	8 June 2023	TÜV SÜD Product Service GmbH Identification number: 0123	TÜV SÜD Product Service GmbH Identification number: 0123	31 December 2028	N/A
Temperature Probe	G1 0664560022 Rev.00	8 June 2023	TÜV SÜD Product Service GmbH Identification number: 0123	TÜV SÜD Product Service GmbH Identification number: 0123	31 December 2028	N/A
Oximeter	G1 0664560022 Rev.00	8 June 2023	TÜV SÜD Product Service GmbH Identification number: 0123	TÜV SÜD Product Service GmbH Identification number: 0123	31 December 2028	N/A
Disposable Blood Pressure Transducers	G1 0664560022 Rev.00	8 June 2023	TÜV SÜD Product Service GmbH Identification number: 0123	TÜV SÜD Product Service GmbH Identification number: 0123	31 December 2028	N/A
Fetal Transduer	G1 0664560022 Rev.00	8 June 2023	TÜV SÜD Product Service GmbH Identification number: 0123	TÜV SÜD Product Service GmbH Identification number: 0123	31 December 2028	N/A