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Aix-en-Provence, 3rd April 2024

Subject: Transition to Regulation (EU) 2017/745 (MDR)

Dear Madam, Sir,

Regulation **(EU) 2017/745 (MDR)** on medical devices has been in effect since **26th May 2021,** replacing Directive 93/42/EEC (MDD). This regulation strengthens the requirements for medical devices with the aim of improving their safety, quality and effectiveness.

MDR is mandatory for **Class I** devices and for new devices that must obtain a CE certificate since **26/05/2021.**

Class Im, Is, IIa, IIb and **III** may benefit from transitional provisions in accordance with Article 120 of the MDR, provided that there is no change in design and/or intended purpose. Under these conditions, EC certificates under Directive 93/42/EEC are still valid until **26/05/2024**.

On 15 March 2023 **Regulation (EU) 2023/607** of the European Parliament and of the Council amended the transitional provisions of Article 120 of MDR 2017/745. This regulation allows an extension of the validity date of CE MDD certificates under certain conditions.

Class Im, Is, IIa, IIb and III may be placed on the market after 26/05/2024 with their EC certificate in accordance with Directive 93/42/EEC accompanied by a manufacturer's declaration in accordance with Regulation (EU) 2023/607.

- Class Im, Is, IIa and IIb devices will be able to benefit from this extension until **31/12/2028.**
- Class IIb implantable and class III devices will be able to benefit from this extension until **31/12/2027.**

In his declaration, the manufacturer certifies having submitted a formal application to his notified body.

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To date, the regulatory situation of devices manufactured by SPENGLER is specified in the following table:

Spengler		
Medical Device Family	Class	Reference
Stethoscopes	I	MDR (EU) 2017/745
Armbands	I	MDR (EU) 2017/745
Aneroids Sphygmomanometers	Im	MDD 93/42/EEC, MDR Article 120
Electronic Sphygmomanometers	IIa	MDD 93/42/EEC, MDR Article 120
DDM		
Medical Device Family	Class	Reference
Stethoscopes	I	MDR (EU) 2017/745
Tourniquet armbands	I	MDR (EU) 2017/745
PNI armbands	I	MDR (EU) 2017/745
Pressure cuff	I	MDR (EU) 2017/745
Manual tourniquet	I	MDR (EU) 2017/745
Aneroids Sphygmomanometers	Im	MDD 93/42/EEC, MDR Article 120
Pressure inflator	Im	MDD 93/42/EEC, MDR Article 120
Pneumatic tourniquet	IIa	MDD 93/42/EEC, MDR Article 120
Mucus aspirator for medical use	IIa	MDD 93/42/EEC, MDR Article 120
ECM		
Medical Device Family	Class	Reference
Heating cradle for medical use	IIb	MDD 93/42/EEC, MDR Article 120
Heating blankets for medical use	IIb	MDD 93/42/EEC, MDR Article 120
Paediatric Heating Pad for medical use	IIb	MDD 93/42/EEC, MDR Article 120

Spengler has filed a formal transition request under Regulation 2023/607 and makes extension self-declaration, in accordance with Regulation 2023/607, of its EC MDD certificates.

In the coming weeks and before May 26, 2024 Spengler will communicate the GMED official letter.

If you have any questions regarding this regulatory transition context, please contact our Quality and Regulatory Affairs department at qualite@spengler.fr .

Kind regards

The Quality/Regulatory Affairs Department