

Fresenius Kabi AG, 61346 Bad Homburg, Germany

To whom it may concern

Fresenius Kabi AG

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Declaration on the application of Regulation (EU) 2023/607 of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

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We,

Fresenius Kabi AG
Else-Kröner-Str. 1
61352 Bad Homburg
Germany

as the holder of Certificates listed below and represented by Heinrich Martens, Vice President Regulatory Affairs and nominated Person Responsible for Regulatory Compliance, herewith confirm:

The products falling within the scope of the below listed certificates issued according to the Directive 93/42/EEC are subject to the scope of the Regulation (EU) 2023/607 amending (EU) 2017/745, in particular the amendment of Article 120:

EC Certificate No.	Directive 93/42/EEC	Product Classification
G1 047402 0083 Rev. 00	Annex II excluding (4)	IIa, IIb or III
G2S 047402 0084 Rev. 00	Annex V	Is
G7 047402 0046 Rev. 01	Annex II (4)	III
G7 047402 0087 Rev. 00	Annex II (4)	III
G1 047402 0077 Rev. 00	Annex II excluding (4)	IIa, IIb or III
G7 047402 0050 Rev. 01	Annex II (4)	III
G1 047402 0082 Rev. 00	Annex II excluding (4)	IIa, IIb or III
G2S 047402 0085 Rev. 00	Annex V	Is

The Regulation (EU) 2023/607 is fully applicable for the products covered by the certificates listed above.

The extended period of validity by virtue of paragraph 2 of the Regulation (EU) 2023/607 of these certificates and the respective Declaration of Conformities until the given dates below is hereby confirmed by Fresenius Kabi AG:

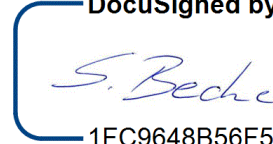
- **31 December 2027** for all class III devices, and for class IIb implantable
- **31 December 2028** for class IIb non-implantable, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

For and on behalf of Fresenius Kabi AG,



i.V.
Heinrich Martens
Vice President Regulatory Affairs
Fresenius Kabi MedTech

DocuSigned by:



i.V. 1FC9648B56F54F8...
Dr. Sabine Becke
Director Regulatory Affairs
Fresenius Kabi MedTech

Bad Hersfeld, 21 November 2023