Declaration of Conformity

Medical Devices Directive 93/42/EEC, Annex II and Section 6 of the German Medical Devices Act
Minisart® HY | Minisart® SRP, Pore Size 0.2 µm, Polytetrafluoroethylene (PTFE) Membrane

Company	Sartorius Stedim Biotech GmbH
Address	August-Spindler-Straße 11 D-37079 Göttingen Federal Republic of Germany
	We herewith declare under our sole responsibility that the device described below meet all requirements of Annex II (excluding section 4) of EU Directive 93/42/EC in combination with the 2007/47/EU and German Act on Medical Devices. We herewith declare that the device described below fulfills the relevant fundamental safety requirements and health regulations specified by the appropriate EU-Directive, with respect to its design and construction and to the version as commercialized. This declaration becomes legally invalid if modifications are performed on the device which have not been certified by Sartorius Stedim Biotech GmbH.
Designation of Device	Syringe Filter, sterile and non-sterile
Model, version	Minisart® HY | Minisart® SRP, Pore Size 0.2 µm, Polytetrafluoroethylene (PTFE) Membrane according to classification IIa
Cat.-No.	sterile versions: 16596--------HYK 16596--------ZSK 17575--------ACK 17575--------ZSK non-sterile versions: 16596----------HYQ 16599----------HYQ
Intended Use	Minisart® syringe filters are used for sterile filtration and/or clarification of low volume air

	and gases. For pharmacy admixture applications of oily solutions in a laboratory environment before use for patient care.	
UMDNS - Code	15-283	Filters, Syringe
GMDN - Code	15283	Filters, Syringe
NBOG BPG 2009-3	MD 0102	Non-active devices for injection, infusion, transfusion and dialysis
Relevant directives of the EU and acts in Germany	Annex II (excluding section 4) of EU Directive 93/42/EC in combination with the 2007/47/EU and German Act on Medical Devices.	
Applied harmonized standards	For the conformity assessment, the applicable harmonized standards and guidelines according to the Regulatory Review were used.	
Additionally applied harmonized standards for sterile products	For the conformity assessment, the applicable harmonized standards and guidelines according to the Regulatory Review were used.	
The company has implemented a Quality management system according to	DIN EN ISO 13485:2016 DIN EN ISO 9001:2015	
Rule according to Annex IX of EU Directive 93/42/EEC as amended by EU Directive 2007/47/EC in combination with § 13 German Act on Medical Devices	Rule 2	
Notified Body	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany	
Registration Number of Notified Body	CE 0123	

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Registration number of certificate issued by Notified Body	G1 075349 0012 Rev. 01
Validity of certificate issued by Notified Body	From April 07th, 2020 until Mai 26th, 2024
This Declaration of Conformity is valid from	April 07th, 2020
This Declaration of Conformity is limited by the validity date of the certificate issued by Notified Body	Mai 26th, 2024

Göttingen, 2020-11-25

Uwe Becker
Managing Director
SSB GmbH

i. A.
Dr. Christian Hoffmann
Manager of Product Compliance
Separation Technologies