



Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 732117 R000

Manufacturer: GlaxoSmithKline Trading Services Limited

Address: 12 Riverwalk Citywest Business Campus Dublin 24 Ireland Single Registration Number: IE-MF-00008351

Scope: See attached Device Schedule

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: 2021-11-25

Date: 2022-04-21

Expiry Date: 2026-11-24 ...making excellence a habit."

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification	
Volumatic Spacer Device	Class IIa	
Diskhaler	Class IIa	
Biopsy Instruments	Class IIa	00.0799

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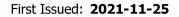
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
25 November 2021	3254304	Issued
Current	3617994	Supplemented – Additions to device group Class IIa – Diskhaler, Biopsy Instruments. Amended-Addition of Sovrin Plastics Ltd and sfm medical devices GmbH. GPE Holding address translated to English.



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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

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Date: 2022-04-21

Critical Subcontractor/Crucial Supplier	Service(s) supplied
GPE Holding GmbH Oderstraße 68 24539 Neumünster Germany	Manufacture
sfm medical devices GmbH Brückenstrasse 5 63607 Wächtersbach Germany	ETO Sterilization Manufacture
Sovrin Plastics Ltd Stirling Road Slough Berkshire SL1 4ST United Kingdom	Manufacture
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