EU Quality Management System Certificate

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-000008351

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.™

EU Quality Management System Certificate

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

MDR 732117 R000

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

First Issued: **2021-11-25** Date: **2022-04-21** Expiry Date: **2026-11-24**

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 732117 R000

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.

First Issued: **2021-11-25** Date: **2022-04-21** Expiry Date: **2026-11-24**

...making excellence a habit.™

EU Quality Management System Certificate

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

List of Critical Subcontractors and Crucial Suppliers

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

MDR 732117 R000

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**

...making excellence a habit.™