

# EU Quality Management System Certificate

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

## MDR 765055 R000

**Manufacturer:** Medisafe UK Limited

**Address:**

Units 7 & 8, Stortford Hall Industrial Park  
Dunmow Road  
Bishop's Stortford  
Hertfordshire  
CM23 5GZ  
United Kingdom

**Single Registration Number:** GB-MF-000019466

**EU Authorised Representative:** STERIS Ireland Limited

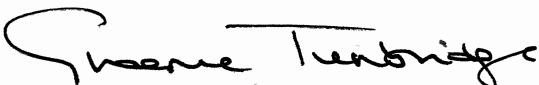
**Address:**

IDA Business & Technology Park  
Tullamore  
Co. Offaly  
R35 X865  
Ireland

**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 devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional 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 Issue Date: **2023-03-10**

Current Issue Date: **2023-03-10**

Starting Validity Date: **2023-03-10**

Expiry Date: **2028-03-09**

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

Device(s)	Risk Classification
MDA0317 - Active non-implantable devices for cleaning, disinfection and sterilisation	Class IIa



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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
Current	3616188	Issued



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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.