EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 739567 R000

Manufacturer: Sheffmed Limited

Address:
Unit 4 Coggin Mill Way
Centurion Business Park
Off Bessemer Way
Rotherham
South Yorkshire
S60 1FB
United Kingdom

Single Registration Number: GB-MF-000004158

EU Authorised Representative: Advena Limited

Address:
Tower Business Centre
2nd Flr.
Tower Street
Swatar
BKR 4013
Malta

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X 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: **2023-12-07**

Current Issue Date: **2024-04-15**

Starting Validity Date: **2024-04-15**

Expiry Date: **2028-12-06**

...making excellence a habit.™

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 739567 R000

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

Device(s)	Risk Classification
ENT Surgery Instruments, Single Use (Suction Cannulas)	Class IIa
ENT Surgery Instruments, Single Use	Class Is
ENT Devices – Otology Devices	Class Is
Gynaecological devices, single use, sterile	Class Is
Tongue Depressors, single use	Class Is
Reusable Surgical Instruments – Surgical Scissors	Class Ir
Reusable Surgical Instruments – General Surgery Forceps	Class Ir
Reusable Surgical Instruments – General Surgery Spreaders & Spatulas	Class Ir
Reusable Surgical Instruments – ENT Nasal & Paranasal Cavity Surgery Instruments	Class Ir
Reusable Surgical Instruments – ENT Ear Surgery Instruments	Class Ir
Reusable Surgical Instruments – ENT Speculums	Class Ir
Reusable Surgical Instruments – ENT Probes	Class Ir
Reusable Diagnostic Instruments - Mirrors	Class Ir
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.	

First Issue Date: **2023-12-07**

Current Issue Date: **2024-04-15**

Starting Validity Date: **2024-04-15**

Expiry Date: **2028-12-06**

...making excellence a habit.™

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 739567 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
2023-12-07	3326928	Issued
Current	30128353	Amended – Change of manufacturer address to Sheffmed Limited, Unit 4 Coggin Mill Way, Centurion Business Park, Off Bessemer Way, Rotherham, South Yorkshire. S60 1FB.

First Issue Date: **2023-12-07**

Current Issue Date: **2024-04-15**

Starting Validity Date: **2024-04-15**

Expiry Date: **2028-12-06**

...making excellence a habit.™

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.