

EU Quality Management System Certificate

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

MDR 766979 R000

Manufacturer: Ivor Shaw Limited Trading as Pennine Healthcare

Address:

300 City Gate
London Road
Derby
DE24 8WY
United Kingdom

Single Registration Number: GB-MF-000004160

EU Authorised Representative: Advena Limited

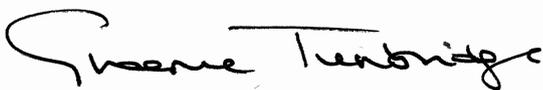
Address:

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 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: **2022-07-28**

Date: **2022-07-28**

Expiry Date: **2027-07-27**

...making excellence a habit.™

EU Quality Management System Certificate

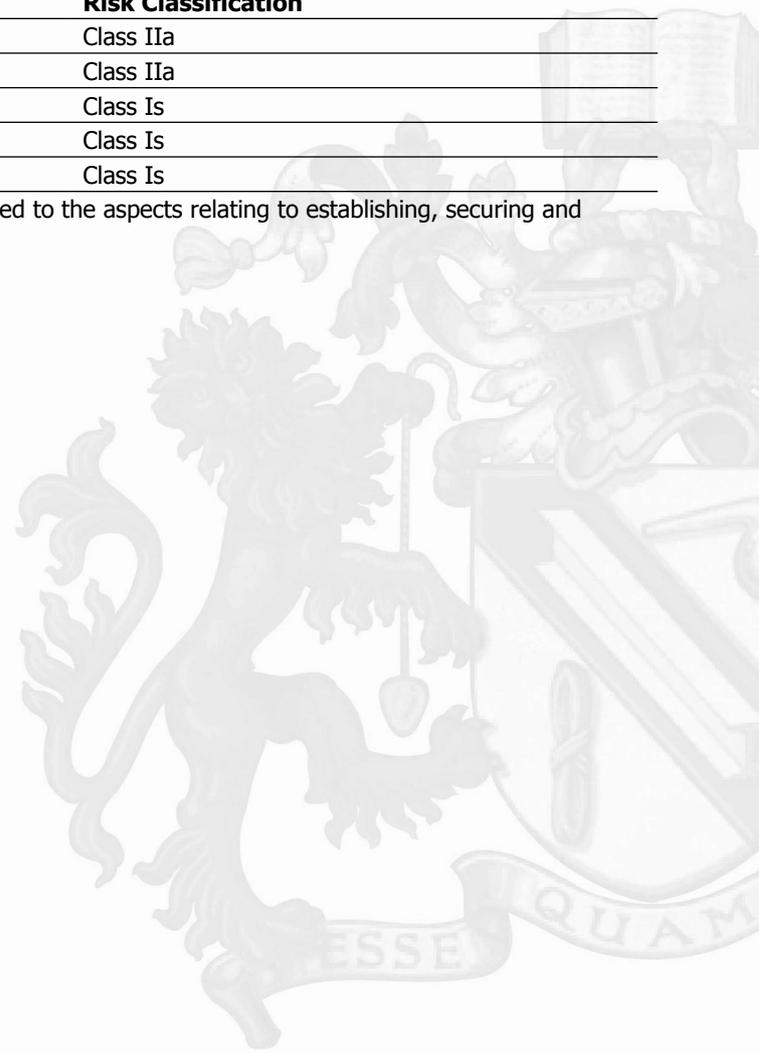
Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 766979 R000

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

Device(s)	Risk Classification
Vacuum and Gravity Drainage Systems	Class IIa
Air/Oxygen Masks and Nasal Cannulas	Class IIa
Suction Connecting Tubes	Class Is
Intermittent Urethral catheters	Class Is
Mucus Extractors, Mucus Specimen Trap	Class Is

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.



First Issued: **2022-07-28**

Date: **2022-07-28**

Expiry Date: **2027-07-27**

...making excellence a habit.™

EU Quality Management System Certificate

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

MDR 766979 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
Current	3637867	Issued



First Issued: **2022-07-28**

Date: **2022-07-28**

Expiry Date: **2027-07-27**

...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.

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 766979 R000

Date: 2022-07-28

Critical Subcontractor/Crucial Supplier	Service(s) supplied
Sterigenics UK Ltd Cotes Park Lane Somercotes Alfreton, DE55 4NJ United Kingdom	ETO Sterilization

...making excellence a habit.™