EU Quality Management System Certificate

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

MDR 807729 R000

Manufacturer: Clonallon Laboratories Limited

Address:
5 Milltown Industrial Estate
Warrenpoint
Newry
BT34 3FN
United Kingdom

Single Registration Number: XI-PR-000033753

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-12-04**

Current Issue Date: **2024-12-04**

Starting Validity Date: **2024-12-04**

Expiry Date: **2029-12-03**

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Device Schedule: Article 22.3 Systems and Procedure Pack

Device(s)	Highest Risk Classification within the System or Procedure Pack
Dressing Packs	Class Is
Suture Removal Packs	Class Is
Surgical Gown Packs	Class Is
Anaesthetic Packs	Class IIa
Caesarean Section Packs	Class IIa
Coloscopy Packs	Class IIa
Dental Packs	Class IIa
Burns Packs	Class Is
Coil Packs	Class IIb
Organ Retrieval Packs	Class IIa
Podiatry Packs	Class Is
Biopsy Packs	Class IIa
I.V. Packs	Class IIa
Colposcopy Packs	Class IIa
Gynae Packs	Class IIa
Orthopaedic Packs	Class III
Catheter Packs	Class IIb
Pacing Packs	Class IIa
Ophthalmic Packs	Class IIa
X-Ray Packs	Class IIa
Drape Packs	Class Is
ENT Packs	Class Is
For Systems and Procedure Packs under Article 22.3, the Notified Body conformity assessment is limited to the aspects relating to ensuring sterility until the sterile packaging is opened or damaged.	

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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	30130884	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.
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