

Quality System Approval CertificateMedical Devices Directive 93/42/EEC

The National Standards Authority of Ireland as a duly designated Notified Body, (identification number **0050**), for the purposes of the European Communities (Medical Devices) Regulations (S.I. No. 252 of 1994)

APPROVES THE QUALITY SYSTEM APPLIED BY

Clonallon Laboratories Ltd

5 Milltown Industrial Estate Warrenpoint Co. Down BT34 3FN Northern Ireland

to the Product Family

Surgical Procedure packs

GMDN Code: 33961

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices Annex V.

The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of

Conformance for this product family is hereby authorised.

Registration Number: 252.1200
Original Approval: 22 April 2020
Last Amended on: 22 April 2020
Remains valid until: 26 May 2024

Signed:

Approved by: Dr. Caroline Dore Geraghty

Director, Medical Devices

Approved by: Dr. Elaine Darcy

European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.

Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.