

Quality System Approval Certificate Medical 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

Medifill Ltd

Unit 2, Plato Business Park **Damastown Industrial Estate Dublin 15** Ireland

to the Product Family

Skin-approximation adhesive (CutisSeal Topical B and H)

GMDN Code: 34164

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:

252.1234

Original Approval:

19 May 2021

Last Amended on:

19 May 2021

Remains valid until:

26 May 2024

Signed:

Dr. Caroline Dore Geraghty

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.

Cert-115: EC Annex V NL A4 (10)