

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

Medivators Inc.

14605 28th Ave N Minneapolis MN 55447 USA

to the Product Family

Peracetic Acid Cold Sterilant (Actril, Minncare and Renalin)

GMDN Code: 40580

on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex II, excluding (4)

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: 252.461

Original Approval: 06 July 2000

Last Amended on: 16 April 2019

Remains valid until: 05 July 2023

Signed:

Approved by: Geraldine Larkin Chief Executive Officer, NSAI Approved by: Dr Caroline Dore Geraghty Director, Medical Devices

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

Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

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