

# NSAI

## 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.*

<b>Registration Number:</b>	<b>252.461</b>
<b>Original Approval:</b>	<b>06 July 2000</b>
<b>Last Amended on:</b>	<b>25 May 2021</b>
<b>Remains valid until:</b>	<b>15 April 2024</b>

**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 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.**

**Supplementary information to AR120 832610** - Non-significant changes approved after the 26<sup>th</sup> May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to: Medivators Inc.  
14605 28th Ave N  
Minneapolis  
MN 55447  
USA

**Date:** 23 September 2025

**Changes Approved:**

Date	Reference Number	Action
23 September 2025	30497421	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Peracetic Acid Cold Sterilant (Minncare). Removal of Actril and Renalin from group. Original NB Certificate Number: 252.461.

23 September 2025

Medivators Inc.  
14605 28th Avenue North  
Minneapolis  
Minnesota  
55447  
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD certificates from 26<sup>th</sup> May 2021.

The transitional provisions specified in IVDR Article 110(3) (as amended by (EU) 2024/1860) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing IVDD certificates from 26<sup>th</sup> May 2022.

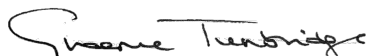
This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) or under IVDR Article 110(3), as applicable, and as per the guidance provided in MDCG 2020-3/MDCG 2022-6.

The related certificate specified below continues to remain valid and devices can be placed on the market based on this certificate as long as the manufacturer complies with the conditions specified in Section 3c of Article 120 of MDR or in Section 3c of Article 110 of IVDR, as applicable.

Original certificate number	BSI reference number	Directive and Annex	Reference Number	Changes approved
252.461	AR120 832610	93/42/EEC Annex II excluding Section 4	30497421	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Peracetic Acid Cold Sterilant (Minncare). Removal of Actril and Renalin from group. Original NB Certificate Number: 252.461.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge  
Senior Vice President, Medical Devices