

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.*

Registration Number:	252.461
Original Approval:	06 July 2000
Last Amended on:	25 May 2021
Remains valid until:	15 April 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 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.



April 2024

Notified Body Confirmation Letter

Reference: NBCL0084.01

**Re: Medivators (Cantel)
Peracetic Acid Cold Sterilant
NSAI File Number 252.461**

To whom it may concern

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

[NSAI.ie](https://www.nsa.ie)

This letter confirms that National Standards Authority of Ireland (NSAI), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0050 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

**Medivators (Cantel)
14605 28th Avenue North Minneapolis, MN 55447 USA**

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before

For confirmation of content of this letter, please email Medical.Devices@nsai.ie
MTF-1039 Rev 2.0



20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

[NSAI.ie](https://www.nsa.ie)

On behalf of the Notified Body

A handwritten signature in black ink that reads "Pamela Bunetto Miller". The signature is written in a cursive, flowing style.

European Medical Device Operations Manager
Medical Devices, NSAI



Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Actril Cold Sterilant 176-02-053	Ila	n/a	CE 0050 252.461
Actril Cold Sterilant 176-02-056	Ila	n/a	CE 0050 252.461
Actril Cold Sterilant 3024982	Ila	n/a	CE 0050 252.461
Minnicare Cold Sterilant 176-01-121	Ila	n/a	CE 0050 252.461
Minnicare Cold Sterilant 176-01-125	Ila	n/a	CE 0050 252.461
Minnicare Cold Sterilant 176-01-129	Ila	n/a	CE 0050 252.461

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
n/a	n/a	n/a	n/a

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.04.03	NBCL0084.01	Initial issue

Manufacturer's Declaration

In relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*¹
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Medivators Inc.
Manufacturer address and contact details	14605 28 th Ave. North Minneapolis, MN 55447, USA Coletta Cohara Director Quality & Regulatory Compliance Coletta_Cohara@STERIS.com
Single Registration Number (SRN) (if available)	No available

Authorised Representative name (if applicable)	Cantel Medical (Italy) S.r.l.
Authorised Representative address and contact details	Via Laurentina, 169 00071 Pomezia (RM) Italy
Single Registration Number (SRN) (if available)	IT-AR-000010078

Notified body name (if applicable)	NSAI <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	0050 <input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	252.461 <input type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-04-15 <input type="checkbox"/> See attached schedule

¹ The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Manufacturer's Declaration

End date of extended validity/transition period	2028-12-31	<input type="checkbox"/> See attached schedule
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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*²
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

Expired *before* 20 March 2023:

- Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device
- A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)
- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Expired/expires *after* 20 March 2023:

- A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

² The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Manufacturer's Declaration

➤ Upclassified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ Quality Management System (QMS)

• *Choose one applicable statement:*

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

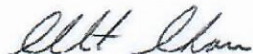
Signed for and on behalf of the manufacturer:

Full Company Name: Medivators Inc.

Location: 14605 28th Ave. North, Minneapolis, MN 55447, USA

Date: 2024-04-04

Signature:



Print Name: Coletta Cohara

Title: Director Quality & Regulatory Compliance

Manufacturer's Declaration

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device (e.g., device name, family/group name device model or catalogue number)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the validity (if applicable)	Notified Body name and number	End date of extended validity/transition period	Substitute Device (if applicable)
Actril Cold Sterilant 176-02-053	252.461	2024-04-15	NSAI 0050	2028-12-31	N/A
Actril Cold Sterilant 176-02-056	252.461	2024-04-15	NSAI 0050	2028-12-31	N/A
Actril Cold Sterilant 3024982	252.461	2024-04-15	NSAI 0050	2028-12-31	N/A
Minnicare Cold Sterilant 176-01-121	252.461	2024-04-15	NSAI 0050	2028-12-31	N/A
Minnicare Cold Sterilant 176-01-125	252.461	2024-04-15	NSAI 0050	2028-12-31	N/A
Minnicare Cold Sterilant 176-01-129	252.461	2024-04-15	NSAI 0050	2028-12-31	N/A