Manufacturer's EU Declaration of Conformity

Manufacturer: Safeguard Medical Technologies Ltd.

Address: The Old Rectory
Hope-Under-Dinmore
Herefordshire
HR6 0PW
United Kingdom

Email: enquiries@safeguardmedical.com

Telephone: +44 (0) 1568 613942

Authorised Rep: Safeguard Technologies Ltd.
Willow Grove
Delgany, Co Wicklow
A63 XY89
Ireland

EU Competent Authority HPRA
Kevin O'Malley House
Medical Devices Department
Earlsfort Centre
Earlsfort Terrace,
Ireland, Dublin D02 XP77

declares and guarantees the product:

Product Name:	Russell Chest Seal®
Intended Use:	The Russell Chest Seal® is designed for the immediate management of an open chest wound and to minimise the risk of developing tension pneumothorax.
Product Code/Number:	IN0680

complies with provision of the EC Directive 93/42/EEC as amended by EC Directive 2007/47/EC which apply to it based on its intended use under the supervision of NSAI, a Notified Body duly authorized by EU Competent Authority to carry out such assessments and carrying the Notified Body number **0050**.

According to the **Annex IX** of the Council Directive 93/42/EEC, rule 4, the product is classified as

Class IIb – sterile, non-invasive medical device

The appropriate registration has been made to MHRA as the competent authority in the UK and the HPRA as the Competent Authority in the EU.

Registered Office Address: Safeguard Medical Technologies Limited
The Old Rectory, Hope-under-Dinmore, Herefordshire, HR6 0PW
Company Number 8623209

Safeguard Medical Technologies Ltd. agrees to develop, implement and maintain the post-production experience monitoring process, including the notification of reportable events under the European Medical Vigilance System Guidelines.

This declaration is based on the **Annex II** of **EC Directive 93/42/EEC.**

Certification of a quality system according to:

Directive **93/42/EEC**, **Annex II** (excluding Section 4) and amending directive **2007/47/EC** - Certificate Number: **252.1244**

EN ISO 13485:2016 - Certificate Number: **MD19.8042**

The listed medical device, its design, manufacturing, distribution complies with the following harmonized standards:

EN ISO 13485:2016	Medical Device – Quality Management Systems
EN ISO 14971:2019	Medical Device – Application of risk management to medical devices
EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied

This declaration of conformity is issued under the sole responsibility of Safeguard Medical Technologies Ltd.

Signed Eva Havelkova Date: May 31, 2021

Eva Havelková – QA/RA Director, Safeguard Medical Technologies Ltd

Revision Number	0
Issue Date	28/05/2021
Change Number	365_21

Version History

DC Number	Revision	Date	Description of Change
365_21	0	28/05/2021	Fist issue of document

Registered Office Address: Safeguard Medical Technologies Limited
The Old Rectory, Hope-under-Dinmore, Herefordshire, HR6 0PW
Company Number 8623209

DTF 006_Declaration of Conformity_RCS

Final Audit Report 2021-05-31

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enquiries@safeguardmedical.com
+44 (0)1568 613 942
The Old Rectory, Hope Under Dinmore
Herefordshire, HR6 0PW, UK
safeguardmedical.com

Manufacturer's Declaration

in relation to 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, 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	Safeguard Medical Technologies Ltd.
Manufacturer address and contact details	The Old Rectory Hope-Under-Dinmore Herefordshire HR6 0PW United Kingdom
Single Registration Number (SRN) (if available)	GB-MF-000012038

Authorised Representative name (if applicable)	Safeguard Technologies Ltd.
Authorised Representative address and contact details	Willow Grove Delgany, Co Wicklow, A63 XY89, Ireland
Single Registration Number (SRN) (if available)	IE-AR-000008867

Notified body name (if applicable)	NSAI National Standards Authority of Ireland
Notified body number (if applicable)	0050
Directive Certificate number(s) to which this confirmation is made (if applicable)	252.1244
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024
End date of extended validity/transition period	31 December 2028

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.

Company Number: 08623209 VAT Number: 175102041

enquiries@safeguardmedical.com
+44 (0)1568 613 942
The Old Rectory, Hope Under Dinmore
Herefordshire, HR6 0PW, UK
safeguardmedical.com

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met

➢ **Directive Certificate(s)** as listed above

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

☒Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is in place in accordance with Section 4.3, second subparagraph of Annex VII (see attached NB Confirmation letter).

☐ 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.
- There are no significant changes in the design and intended purpose.
- 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:

Safeguard Medical Technologies Ltd.

Hereford, 05th February 2024

Eva Havelkova

Eva Havelková

Sr. Director, International QARA

Company Number: 08623209 VAT Number: 175102041

January 2024

Notified Body Confirmation Letter

Reference: NBCL0079.01

Re: Safeguard Medical Technologies Ltd.
Chest Seal Products Family
NSAI File Number 745.113

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

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:

Safeguard Medical Technologies Ltd.
The Old Rectory, Hope under Dinmore, Herefordshire, HR6 0PW, United Kingdom
SRN Number : GB-MF-000012038

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.

HEAD OFFICE

1 Swift Square,
Northwood, Santry,
Dublin 9, Ireland
T +353 (0)1 807 3800
F +353 (0)1 807 3844
E certification@nsai.ie

NSAI.ie

REGIONAL CENTRE

Limerick
Plassey Park Road
Castletroy, Limerick

1 Swift Square,
Northwood, Santry,
Dublin 9, Ireland
T +353 61 330 708
F +353 61 330 698

INTERNATIONAL OFFICE

NSAI Inc.
20 Trafalgar Square
Suite 603
Nashua, NH 03063

T +1 603 882 4412
F +1 603 882 1985

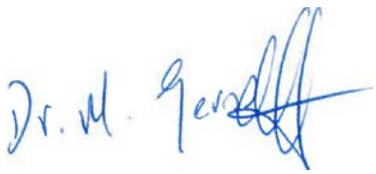
NSAIinc.com

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 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)

On behalf of the Notified Body



Dr Majella Geraghty
European Medical Device Operations Manager
Medical Devices, NSAI

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Northwood, Santry,
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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
5060483570680WK	IIb	N/A	NSAI 0050 252.1244

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

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.01.19	NBCL0079.01	Initial issue

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

Safeguard Medical Technologies Ltd.

The Old Rectory
Hope-Under-Dinmore
Herefordshire HR6 0PW
United Kingdom

to the Product Family

Russell Chest Seal®

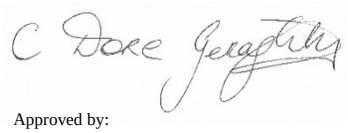
GMDN Code: 46424

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:	**252.1244**
Original Approval:	**07 April 2021**
Last Amended on:	**07 April 2021**
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 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.

19th May 2021

Ms Sarah Gallagher
Safeguard Medical Technologies Ltd.
The Old Rectory
Hope-Under-Dinmore, Herefordshire HR6 0PW
United Kingdom

RE: Russell Chest Seal®

Dear Ms Gallagher

Further to your recent significant change notification, I am happy to inform you that the above Product Family, file number 252.1244**,** has been amended as follows:

The company name is changing from 'Prometheus Medical Technologies' to 'Safeguard Medical Technologies Ltd.'

The AR name and address changed to:
Safeguard Technologies Ltd
Willow Grove,
Delgany, Co Wicklow,
A63 XY89
Ireland

Approval conditions: None

Our reference for this amendment is 252.1244.01. This amendment takes effect from **19th May 2021**.

The NSAI Notified Body number, 0050, may be used on the additional model(s) / trade name(s) above, in conjunction with the CE Marking of conformance.

Yours Sincerely

Elaine Darcy
European Medical Device Operations Manager
Medical Devices
NSAI

HEAD OFFICE

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Manufacturer's EU Declaration of Conformity

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declares and guarantees the product:

Product Name:	Russell Chest Seal®
Intended Use:	The Russell Chest Seal® is designed for the immediate management of an open chest wound and to minimise the risk of developing tension pneumothorax.
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According to the **Annex IX** of the Council Directive 93/42/EEC, rule 4, the product is classified as

Class IIb – sterile, non-invasive medical device

The appropriate registration has been made to MHRA as the competent authority in the UK and the HPRA as the Competent Authority in the EU.

Registered Office Address: Safeguard Medical Technologies Limited
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Safeguard Medical Technologies Ltd. agrees to develop, implement and maintain the post-production experience monitoring process, including the notification of reportable events under the European Medical Vigilance System Guidelines.

This declaration is based on the **Annex II** of **EC Directive 93/42/EEC.**

Certification of a quality system according to:

Directive **93/42/EEC**, **Annex II** (excluding Section 4) and amending directive **2007/47/EC** - Certificate Number: **252.1244**

EN ISO 13485:2016 - Certificate Number: **MD19.8042**

The listed medical device, its design, manufacturing, distribution complies with the following harmonized standards:

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EN ISO 15223-1:2016	Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied

This declaration of conformity is issued under the sole responsibility of Safeguard Medical Technologies Ltd.

Signed Eva Havelkova Date: May 31, 2021

Eva Havelková – QA/RA Director, Safeguard Medical Technologies Ltd

Revision Number	0
Issue Date	28/05/2021
Change Number	365_21

Version History

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