EC Certificate Production Quality Assurance System: Certificate GB20/965681

The management system of

Prosum Medical Ltd

67 Ayres Road, Old Trafford, Manchester, M16 9NH, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 04 January 2021until 07 December 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 08 December 2015
and first certified by SGS Belgium NV since 24 April 2020

Certification is based on reports numbered GB/PC/ 240852

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Prosum Medical Ltd

Directive 93/42/EEC

on medical devices, Annex V

Issue 3

Detailed scope

Annex V:
Blood Collecting needles, Dental needles, Extension sets, Hypodermic needles, IV Catheters, Infusion sets, Insulin pen Needles, Scalp vein sets, Sterile syringes for use with or without needles, Syringes for insulin

Class I sterile : Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Angiography Syringes
Irrigation Syringes
Dispensing Hypodermic Needles (Blunt Fill Needles)

For placing on the market of Class IIb covered by this certificate, an EC Type Examination Certificate according to Annex III is required

Corrigendum to Certificate GB20/965681

Prosum Medical Limited

67 Ayres Road, Old Trafford, Manchester, M16 9NH, UK

Scope:

Annex V:
Blood Collecting needles, Dental needles, Extension sets, Hypodermic needles, IV Catheters, Infusion sets, Insulin pen Needles, Scalp vein sets, Sterile syringes for use with or without needles, Syringes for insulin

Class I sterile : Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Angiography Syringes
Irrigation Syringes
Dispensing Hypodermic Needles (Blunt Fill Needles)

This corrigendum is only valid together with accompanying 93/42/EEC certificate issue 3

Correction Date	Correction
Change approved by SGS on 16/08/2021	Change of company address from '67 Ayres Road, Old Trafford, Manchester, M16 9NH, United Kingdom to 'Unit 14 Cowley Mill Road, Uxbridge, UB8 2DB, United Kingdom'

Authorised by

Global Medical Devices Certification Manager

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 **f** +32 (0)3 545-48-49 www.sgs.com

Prosum Medical Limited
Unit 14 Cowley Mill Road,
Uxbridge
Greater London
UB8 2DB
United Kingdom

27/03/2024

Confirmation Letter Reference: CLNB1639 - GBPC 240852

To whom it may concern,

Confirmation of receipt 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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:

Prosum Medical Limited
Unit 14 Cowley Mill Road,
Uxbridge
Greater London
UB8 2DB
United Kingdom
SRN: GB-MF-000028725

EU representative:
Metisce Ltd.
Agapironos 1,
JNT
1076, Nicosia
Cyprus
SRN: CY-AR-000035644

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 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 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;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 SGS Belgium NV NB1639,

Ian How
PP
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone: +41 22 739 98 58

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**:**

MDR Device Sub-Group Name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
Irrigation Syringe Catheter Tip 50560930S089	Class Is	Irrigation Syringes	N/A	GB20/965681; NB1639
Syringe without Needle Luer Slip / Luer Lock 50560930S089	Class Is	Sterile Syringes for use with or without Needles	N/A	GB20/965681; NB1639
Polycarbonate Syringe Luer Lock 50560930S089	Class Is	Sterile Syringes for use with or without Needles	N/A	GB20/965681; NB1639
Tuberculin Syringe 1ml Luer Slip / Luer Lock 50560930S089	Class Is	Sterile Syringes for use with or without Needles	N/A	GB20/965681; NB1639
Zero Residual Syringe 0.3ml Luer Slip / Luer Lock 50560930S089	Class Is	Sterile Syringes for use with or without Needles	N/A	GB20/965681; NB1639
Zero Residual Syringe 0.2ml Luer Slip / Luer Lock 50560930S089	Class Is	Sterile Syringes for use with or without Needles	N/A	GB20/965681; NB1639
Syringes (sterile and without needle) for use with pump 50560930S089	Class IIa	Sterile Syringes for use with or without Needles	N/A	GB20/965681; NB1639
Blunt Fill Needle 50560930BN8G	Class Is	Blunt Fill Needles	N/A	GB20/965681; NB1639

MDR Device Sub-Group Name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
Blunt Fill Needle, with filter 50560930BN8G	Class Is	Blunt Fill Needles	N/A	GB20/965681; NB1639
Blunt Fill Needle, with filter, silicon free 50560930BN8G	Class Is	Blunt Fill Needles	N/A	GB20/965681; NB1639
Blood collection multi-sample needle w. Holder 50560930BC7S	Class IIa	Blood Collection Needles	N/A	GB20/965681; NB1639
Blood collection Safety Multi-sample Needle 50560930BC7S	Class IIa	Blood Collection Needles	N/A	GB20/965681; NB1639
Blood collection Safety Multi-sample Needle w. Holder 50560930BC7S	Class IIa	Blood Collection Needles	N/A	GB20/965681; NB1639
Blood Collection Set Winged Needle w. Luer Adaptor 50560930BC7S	Class IIa	Blood Collection Needles	N/A	GB20/965681; NB1639
Blood Collection Set Winged Needle w. Luer Adaptor & Holder 50560930BC7S	Class IIa	Blood Collection Needles	N/A	GB20/965681; NB1639
Blood Collection Set Safety Winged Needle w. Luer Adaptor 50560930BC7S	Class IIa	Blood Collection Needles	N/A	GB20/965681; NB1639
Blood Collection Set Safety Winged Needle w. Luer Adaptor & Holder 50560930BC7S	Class IIa	Blood Collection Needles	N/A	GB20/965681; NB1639

MDR Device Sub-Group Name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
Blood Collection accessories 50560930BC7S	Class IIa	Blood Collection Needles	N/A	GB20/965681; NB1639
Dental Needles 50560930DN8N	Class IIa	Dental Needles	N/A	GB20/965681; NB1639
Extension set, PVC 50560930EXTUV	Class IIa	Extension Sets	N/A	GB20/965681; NB1639
Extension set, PE 50560930EXTUV	Class IIa	Extension Sets	N/A	GB20/965681; NB1639
Extension set with stopcock 50560930EXTUV	Class IIa	Extension Sets	N/A	GB20/965681; NB1639
Extension set with stopcock, needlefree connectors 50560930EXTUV	Class IIa	Extension Sets	N/A	GB20/965681; NB1639
Extension set with needlefree connectors, filter 50560930EXTUV	Class IIa	Extension Sets	N/A	GB20/965681; NB1639
Single lumen Extension set with needlefree connectors 50560930EXTUV	Class IIa	Extension Sets	N/A	GB20/965681; NB1639
Double lumen Extension set with needlefree connectors 50560930EXTUV	Class IIa	Extension Sets	N/A	GB20/965681; NB1639
Triple lumen Extension set with needlefree connectors 50560930EXTUV	Class IIa	Extension Sets	N/A	GB20/965681; NB1639
Quad lumen Extension set with needlefree connectors 50560930EXTUV	Class IIa	Extension Sets	N/A	GB20/965681; NB1639

MDR Device Sub-Group Name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
Hypodermic Needle 50560930NPP	Class IIa	Hypodermic Needles	N/A	GB20/965681; NB1639
Safety Hypodermic Needle 50560930NPP	Class IIa	Hypodermic Needles	N/A	GB20/965681; NB1639
Hypodermic Needle, Low dead-space 50560930NPP	Class IIa	Hypodermic Needles	N/A	GB20/965681; NB1639
Gravity Administration Set 50560930INFTP	Class IIa	Infusion Sets	N/A	GB20/965681; NB1639
Gravity Blood Administration Set 50560930INFTP	Class IIa	Infusion Sets	N/A	GB20/965681; NB1639
Gravity Burette Set 50560930INFTP	Class IIa	Infusion Sets	N/A	GB20/965681; NB1639
Administration Set for pump 50560930INFTP	Class IIa	Infusion Sets	N/A	GB20/965681; NB1639
Pen Needles 50560930IPNUD	Class IIa	Insulin Pen Needle	N/A	GB20/965681; NB1639
Safety Pen Needles 50560930IPNUD	Class IIa	Insulin Pen Needle	N/A	GB20/965681; NB1639
IV Catheter Straight 50560930IVCU9	Class IIa	IV Catheters	N/A	GB20/965681; NB1639
IV Catheter with Wing 50560930IVCU9	Class IIa	IV Catheters	N/A	GB20/965681; NB1639
IV Catheter Ported with Wing 50560930IVCU9	Class IIa	IV Catheters	N/A	GB20/965681; NB1639
Safety IV Catheter Straight 50560930IVCU9	Class IIa	IV Catheters	N/A	GB20/965681; NB1639

MDR Device Sub-Group Name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
Safety IV Catheter Ported with Wing 50560930IVCU9	Class IIa	IV Catheters	N/A	GB20/965681; NB1639
Syringe with Needle, Luer Slip / Luer Lock 50560930S18B	Class IIa	Sterile syringe for use with or without needles	N/A	GB20/965681; NB1639
Syringe with Safety Needle, Luer Slip / Luer Lock 50560930S18B	Class IIa	Sterile syringe for use with or without needles	N/A	GB20/965681; NB1639
Safety Syringe with Needle, Fixed Needle, safety sleeve 50560930S18B	Class IIa	Sterile syringe for use with or without needles	N/A	GB20/965681; NB1639
Syringe with Fixed Needle 50560930S18B	Class IIa	Sterile syringe for use with or without needles	N/A	GB20/965681; NB1639
Syringe with Needle, RUP Plunger 50560930S18B	Class IIa	Sterile syringe for use with or without needles	N/A	GB20/965681; NB1639
Tuberculin Syringe, Fixed Needle 50560930S18B	Class IIa	Sterile syringe for use with or without needles	N/A	GB20/965681; NB1639
Tuberculin Syringe, Detachable Needle 50560930S18B	Class IIa	Sterile syringe for use with or without needles	N/A	GB20/965681; NB1639
Zero Residual Syringe with Needle, Luer Slip / Luer Lock 50560930S18B	Class IIa	Sterile syringe for use with or without needles	N/A	GB20/965681; NB1639
U-100 Insulin Syringe Insulin Syringe Fixed Needle 50560930INSUH	Class IIa	Syringes for insulin	N/A	GB20/965681; NB1639

MDR Device Sub-Group Name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
U-100 Insulin Syringe without Needle, Luer Lock / Luer Slip50560930INSUH	Class IIa	Syringes for insulin	N/A	GB20/965681; NB1639
U-40 Insulin Syringe Fixed Needle 50560930INSUH	Class IIa	Syringes for insulin	N/A	GB20/965681; NB1639
Safety Insulin Syringe Fixed Needle 50560930INSUH	Class IIa	Syringes for insulin	N/A	GB20/965681; NB1639
Scalp Vein Set / Winged Infusion Set 50560930SVAK	Class IIa	Scalp vein Set	N/A	GB20/965681; NB1639
Safety Infusion Set Straight With Wings 50560930SVAK	Class IIa	Scalp vein Set	N/A	GB20/965681; NB1639

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

27/03/2024	Version 1	Initial issue