



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 2021 until 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

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LPMD5008 - Certificate CE1639 Annex V - EN rev. 01

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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

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SGS Belgium NV

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