EC CERTIFICATE
Production Quality Assurance

Certificate No.:	Project No.:	Valid Until
10000370555-PA-NA-DNK	PRJN-188661-2020-PA-DNK	26 May 2024

This is to certify that the quality system of:

ArcRoyal
Virginia Road, Kells, Co. Meath, Ireland

For production and final product inspection/testing of:

Pressure lines (pressure monitoring), High Pressure Lines, Coronary Introducer Needles and sterile single use light handle cover, angiography Device, manifolds, control syringes, inflation device, infusion/administration sets, surgical skin markers, and electrosurgical tip cleaner.

Sterilization of system and procedure packs according to article 12, section 3.

Has been assessed with respect to:

The conformity assessment procedure described in Annex V of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 12 July 2021

Check Validity

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Hazem Tinawi
Technical Reviewer

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Transfer of Presafe Denmark A/S (NB 0543) Certificate No. DGM-027 to DNV Product Assurance AS (NB 2460)	25 May 2021
1.0	To include missing part of scope	12 July 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Pressure Monitoring Lines	Pressure Monitoring Line, Male/Female, 15 cm; Pressure Monitoring Line, Male/Female, 30 cm; Pressure Monitoring Line, Male/Female, 90 cm; Pressure Monitoring Line, Male/Female, 120 cm; Pressure Monitoring Line, Male/Female, 150 cm	IIa
High Pressure Lines	Injector Line 1200 psi 75 cm Luer Lock; Injector Line 1200 psi 120 cm Luer Lock; Injector Line 1200 psi 25 cm Rotating Adaptor; Injector Line 1200 psi 75 cm Rotating Adaptor; Injector Line 1200 psi 120 cm Rotating Adaptor; Injector Line 1200 psi 50 cm Rotating Adaptor; Braided High Pressure Line, fixed, female with wing 10”; Braided High Pressure Line, fixed, female with wing 30”; Braided High Pressure Line, fixed, female with wing 48”; Braided High Pressure Line, fixed, female, rotating adaptor, 20”; Braided High Pressure Line, fixed, female, rotating adaptor, 30”; Braided High Pressure Line, fixed, female, rotating adaptor, 48”	IIa
Coronary Introducer Needle	Coronary Guidewire Introducer Needle 19ga x 38 mm, Coronary Guidewire Introducer Needle 21ga x 38 mm, Coronary Guidewire Introducer Needle 18ga x 77 mm, Coronary Guidewire Introducer Needle 18ga x 70 mm	IIa
Angiography Device	PTCA Accessory Kit; Y-Connector, single; Y-Connector, double; Torque device	Is

Manifolds	Manifold 2-port 250 psi RH RA ON, Manifold 2-port 250 psi RH RA OFF, Manifold 3-port 250 psi RH RA OFF	Is
Control Syringe	Control Syringe 10 mL, Male, Luer Lock with thumb & finger rings; Control Syringe 10 mL, Male, Rotating Adaptor with thumb & finger rings	Is
Infusion/ Admininstration Set	Admin Set AAA	Is
Inflation Device	Inflation device	Is
Light Handle cover	Light Handle Cover 1/pkt S; Light Handle Cover 2/pkt S	Is
Surgical Skin Markers	Skin Marker Std Tip, Skin Marker Fine Tip	Is
Electrosurgical tip cleaner	Cautery Tip Cleaner	Is

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	**Address**
ArcRoyal	Virginia Road, Kells, Co. Meath, Ireland

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate