

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10000362744-PA-NA-NOR Rev.0.0

Project No.:
PRJC-593193-2018-MSL-NOR

Valid Until:
26 May 2024

This is to certify that the quality system of:

Amon AB

Industrivägen 8 - 362 54
Urshult, Sweden

For design, production and final product inspection/testing of:
**PIPES AND FITTINGS FOR MEDICAL GAS PIPELINE
SYSTEMS**

Has been assessed with respect to:
**THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN
ANNEX II EXCLUDING SECTION 4 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, 29 June 2020



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



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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	Original Certificate	29 June 2020

Products covered by this Certificate:

Product Description	Product Name	Class
SMCUR – 8mm – 108mm	SAMedical® Copper Tube 2.5 mg/m ²	IIa
SMCURS – 8mm – 108mm	SAMedical® Copper Tube 2.5 mg/m ² "Short"	IIa
SMCUREU – 8mm – 108mm	SAMedical® Copper EU Tube 20 mg/m ²	IIa
SMCUB90 – 8mm – 108mm	SAMedical® Copper Street Elbow 90° 2.5 mg/m ²	IIa
SMCUV90 – 8mm – 108mm	SAMedical® Copper Elbow 90° 2.5 mg/m ²	IIa
SMCUB45 – 10mm – 54mm	SAMedical® Copper Street Elbow 45° 2.5 mg/m ²	IIa
SMCUV45 – 12mm – 88.9mm	SAMedical® Copper Elbow 45° 2.5 mg/m ²	IIa
SMCUV90 – 8mm – 70mm	SAMedical® Copper Elbow 90° 2.5 mg/m ²	IIa
SMCUB90 – 10mm – 54mm	SAMedical® Copper Street Elbow 90° 2.5 mg/m ²	IIa
SMCUT – 8mm – 108mm	SAMedical® Copper Equal tee 2.5 mg/m ²	IIa
SMCUTF – 12mm – 108mm	SAMedical® Copper Reduced branch tee 2.5 mg/m ²	IIa
SMCUFM – 10mm – 108mm	SAMedical® Copper Reducing coupling 2.5 mg/m ²	IIa
SMCUFN – 8mm – 70mm	SAMedical® Copper Fitting reducer 2.5 mg/m ²	IIa
SMCUM – 8mm – 108mm	SAMedical® Copper Straight coupling 2.5 mg/m ²	IIa
SMCUH – 8mm – 108mm	SAMedical® Copper Stop end 2.5 mg/m ²	IIa
SMCUSS – 8mm – 114mm	SAMedical® CU to SS transition tube 2.5 mg/m ²	IIa
SMSSR – 12mm – 104mm	SAMedical® Stainless-steel Tube 2.5 mg/m ²	IIa
SMSSB90 – 12mm – 104mm	SAMedical® Stainless-steel Bend 90° 2.5 mg/m ²	IIa
SMSSB45 – 12mm – 104mm	SAMedical® Stainless-steel Bend 45° 2.5 mg/m ²	IIa
SMSST – 12mm – 104mm	SAMedical® Stainless-steel Tee 2.5 mg/m ²	IIa
SMSSTF – 12mm – 104mm	SAMedical® Stainless-steel Reduced tee 2.5 mg/m ²	IIa
SMSSF – 12mm – 104mm	SAMedical® Stainless-steel Reducer 2.5 mg/m ²	IIa
SMSSH – 12mm – 104mm	SAMedical® Stainless-steel Cap 2.5 mg/m ²	IIa
SMSSB90S – 12mm – 104mm	SAMedical® Stainless-steel Bend 90° 2.5 mg/m ² "Short"	IIa

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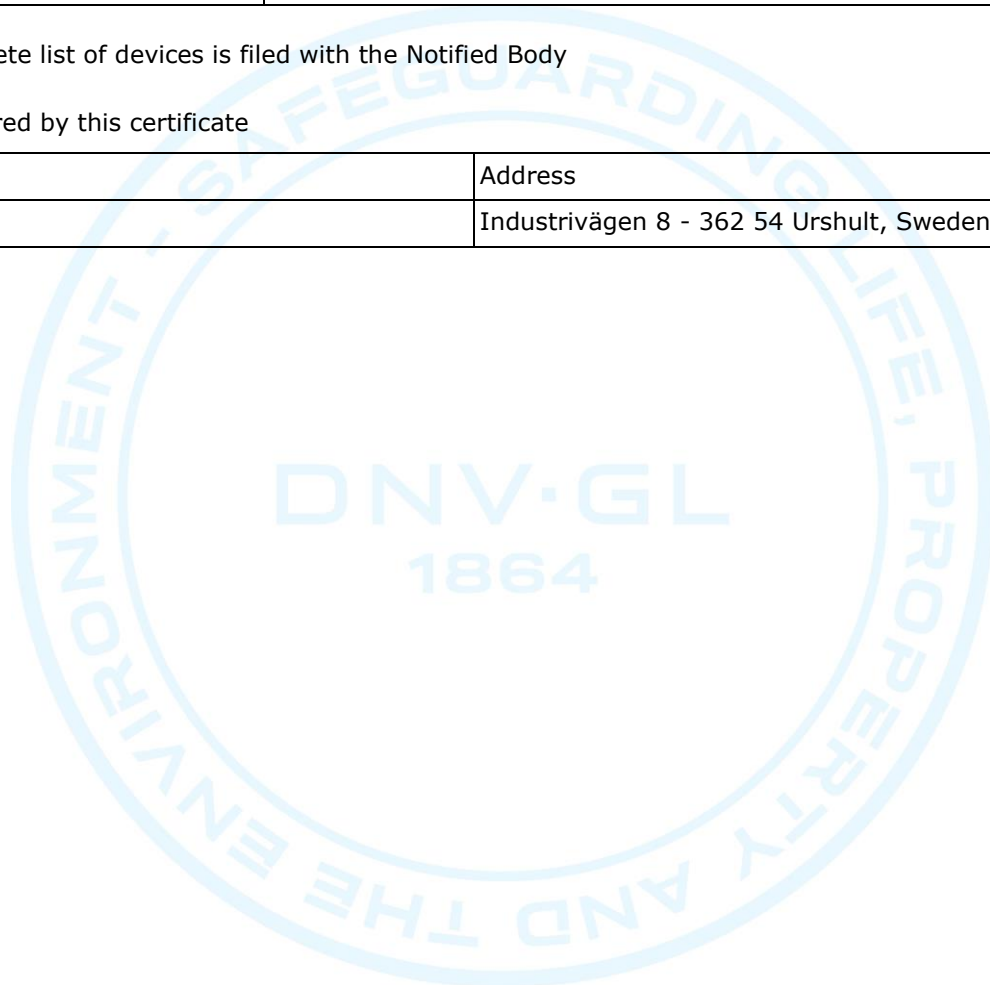
Valid Until:
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SMSSB45S – 12mm – 104mm	SAMedical® Stainless-steel Bend 45° 2.5 mg/m ² "Short"	IIa
SMSSTS – 12mm – 104mm	SAMedical® Stainless-steel Tee 2.5 mg/m ² "Short"	IIa
SMSSTFS – 12mm – 104mm	SAMedical® Stainless-steel Reduced tee 2.5 mg/m ² "Short"	IIa
SMSSFS – 12mm – 104mm	SAMedical® Stainless-steel Reducer 2.5 mg/m ² "Short"	IIa
SMSSHS – 12mm – 104mm	SAMedical® Stainless-steel Cap 2.5 mg/m ² "Short"	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Amon AB	Industrivägen 8 - 362 54 Urshult, Sweden



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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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate