EC CERTIFICATE
Full Quality Assurance System

Certificate no.:
248911-2017-CE-FIN-NA-PS

Initial certification date:
02 November 2017

Valid Until:
27 May 2024

This is to certify that the management system of
SALOFA OY
Örninkatu 15, 24100 Salo, Finland

For design, production and final product inspection/testing of:
Sterile Disposable Medical Devices

has been assessed and found to comply 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

Place and date:
Høvik, 25 May 2021

For the issuing office:
DNV Product Assurance AS - Notified Body 2460
Veritasveien 3, 1363 Høvik, Norway

Mariann Jeremiassen
Principal Assessor

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

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**	**Issued Date**
0.0	Replaces the Certificate 94412-2011-CE-FIN-NA Rev. 1.0 (NB 0434), following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460)	2017-11-02
1.0	**Recertification**	**2021-05-25**

Products covered by this Certificate:		
Product Description	**Product Name**	**Class**
Liquid and gas transfer lines and sets	• CT Refill Sets • CT Patient Lines	IIa

Sites covered by this certificate	
Site Name	**Site Address**
Salofa Oy	Örninkatu 15, 24100 Salo, Finland

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. 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.