

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Lobeck Medical AG
Industriestrasse 30
5070 Frick
Switzerland

Coverage of Certificate: Manufacture and final inspection

Product category: Blood lancets

Valid until: 23rd January 2022

The manufacturer's quality system for the manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex V Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex V in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 23rd January 2017


Aliisa Siljander







Tiina Riihimäki

Certificate no.
VTT-C-11860-01-1191-614-16

Notified Body no. 0537:
VTT Expert Services Ltd
P.O. BOX 345 (Tekniikankatu 1)
FI-33101 TAMPERE, FINLAND
Tel.+358 20 722 111

Attachment 1 to the Certificate number: VTT-C-11860-01-1191-614-16

Manufacturer:	Lobeck Medical AG Industriestrasse 30, 5070 Frick Switzerland								
Activity and product category:	Manufacture and final inspection of blood lancets. GMDN-code(s): 61579								
Products:	<p>The certificate covers the following products:</p> <table border="1"> <thead> <tr> <th><i>Name</i></th> <th><i>Brand name</i></th> <th><i>Model</i></th> <th><i>Class</i></th> </tr> </thead> <tbody> <tr> <td>Blood lancet, sterile</td> <td>MediSmart® Lancets</td> <td>MS 205, MS 305</td> <td>IIa</td> </tr> </tbody> </table>	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	<i>Class</i>	Blood lancet, sterile	MediSmart® Lancets	MS 205, MS 305	IIa
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Blood lancet, sterile	MediSmart® Lancets	MS 205, MS 305	IIa						
Date:	Valid from: 23 rd January 2017								
	 <p>  Aliisa Siljander  Tiina Riihimäki </p>								

VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 93/42/EEC.

VTT EXPERT SERVICES LTD

Medical Devices
Tekniikankatu 1, Tampere
P.O. BOX 345, FI-33101 TAMPERE, FINLAND

Tel. +358 20 722 111
www.vtt.fi

name.surname@vtt.fi
Business ID 2297513-2