

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

Manufacturer: Lobeck Medical AG
Industriestrasse 30
5070 Frick
Switzerland

Coverage of Certificate: Design, manufacture and final inspection

Product category: Medical devices for the
measurement of blood sugar

Valid until: 23rd January 2022

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 98/79/EC as set out in Annex IV Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex IV in Directive 98/79/EC. Products covered by the certificate are specified in the attachment(s).

Valid from: 23rd January 2017


Aliisa Siljander




Tiina Riihimäki

Certificate no.
VTT-C-11859-02-1191-613-16

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-11859-02-1191-613-16

Manufacturer:	Lobeck Medical AG Industriestrasse 30, 5070 Frick Switzerland																											
Activity and product category:	Design, manufacture and final inspection of medical devices for the measurement of blood sugar. GMDN-code(s): 30854																											
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> </tr> </thead> <tbody> <tr> <td>Blood glucose monitoring system</td> <td>Medismart® Ruby</td> <td>MS510-010</td> </tr> <tr> <td>Blood glucose meter</td> <td>Medismart® Ruby</td> <td>MS520-010</td> </tr> <tr> <td>Blood glucose test strips</td> <td>Medismart® Ruby</td> <td>MS560-010 MS570-010</td> </tr> <tr> <td>Glucose control solutions</td> <td>Medismart® Ruby</td> <td>MS550-010</td> </tr> <tr> <td>Blood glucose monitoring system</td> <td>Medismart® Sapphire</td> <td>MS 410-010/020</td> </tr> <tr> <td>Blood glucose meter</td> <td>Medismart® Sapphire</td> <td>MS 420-010/020</td> </tr> <tr> <td>Blood glucose test strips</td> <td>Medismart® Sapphire</td> <td>MS 460-010/020 MS 470-010/020</td> </tr> <tr> <td>Glucose control solutions</td> <td>Medismart® Sapphire</td> <td>MS 450-010</td> </tr> </tbody> </table>	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	Blood glucose monitoring system	Medismart® Ruby	MS510-010	Blood glucose meter	Medismart® Ruby	MS520-010	Blood glucose test strips	Medismart® Ruby	MS560-010 MS570-010	Glucose control solutions	Medismart® Ruby	MS550-010	Blood glucose monitoring system	Medismart® Sapphire	MS 410-010/020	Blood glucose meter	Medismart® Sapphire	MS 420-010/020	Blood glucose test strips	Medismart® Sapphire	MS 460-010/020 MS 470-010/020	Glucose control solutions	Medismart® Sapphire	MS 450-010
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VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 98/79/EC.