

QUALITY SYSTEM

CERTIFICATE

ISO 13485:2016

HMM Diagnostics GmbH

Friedrichstrasse 89, D-69221 Dossenheim

GERMANY

VTT Expert Services Ltd has assessed the company's quality system and found that it meets the requirements of ISO 13485:2016.

This certificate covers the following functions:

**Design, production, final inspection and sales of
medical devices for the measurement of blood sugar,
blood lancets, and blood pressure monitors**

Issued:

25th April 2018

Valid until:

25th April 2021

First issued:

22nd March 2013



Olli Kakkonen
Certifier
VTT Expert Services Ltd



Mikko Soikkeli
Lead Auditor
VTT Expert Services Ltd

Certificate nr.
VTT-C-12296-60-18



Certification body:
VTT Expert Services Ltd
P.O.Box 345, FI-33101 Tampere
FINLAND
Tel. +358 20 722 111

QUALITY SYSTEM

EC-CERTIFICATE

Directive 98/79/EC

Manufacturer: HMM Diagnostics GmbH
Friedrichstrasse 89
D-69221 Dossenheim
Germany

Coverage of Certificate: Design, manufacture and final inspection

Product category: Blood glucose test devices for self-testing

Valid until: 22nd March, 2023

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, 22nd March 2018



Olli Kakkonen







Mikko Soikkeli

Certificate no.
VTT-C-12297-02-1163-634-18

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-12297-02-1163-634-18

Manufacturer:	HMM Diagnostics GmbH Friedrichstrasse 89, 69221 Dossenheim, Germany		
Activity and product category:	Design, manufacture and final inspection; blood glucose test devices for self-testing. GMDN-code: 62537.		
Products:	The certificate covers the following products:		
	<i>Name</i>	<i>Brand name</i>	<i>Model</i>
	- Blood Glucose Monitoring System	▪ smartLAB	<ul style="list-style-type: none"> • sprint • genie • genie+ • global • mini • sprint nG • mini nG • global W nG • hbgm
		▪ Esysa ▪ DiaAssist	
	- Blood Glucose Meter	▪ smartLAB	<ul style="list-style-type: none"> • sprint • genie • genie+ • global • mini • sprint nG • mini nG • global W nG • hbgm
		▪ Esysa ▪ DiaAssist	
	- Blood Glucose Test Strip	▪ smartLAB	<ul style="list-style-type: none"> • Pro • nG
		▪ Esysa ▪ DiaAssist	
	- Glucose Control Solution	▪ smartLAB	<ul style="list-style-type: none"> - • nG
		▪ Esysa	
Date:	Valid from 22 nd March 2018		
	 Olli Kakkonen		 Mikko Soikkeli



VTT Expert Services Ltd is Notified Body no. 0537 under Council Directive 98/79/EC.

VTT EXPERT SERVICES LTD

Medical Devices
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P.O. BOX 345, FI-33101 TAMPERE, FINLAND
V.1.2 / 26.2.2017

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www.vtt.fi
Business ID 2297513-2

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: HMM Diagnostics GmbH
Friedrichstrasse 89
D-69221 Dossenheim
Germany

Coverage of Certificate: Manufacture and final inspection

Product category: Blood lancets, blood pressure monitors

Valid until: 22nd March, 2023

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 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, 22nd March 2018


Olli Kakkonen







Mikko Soikkeli

Certificate no.
VTT-C-12298-01-1163-635-18

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-12298-01-1163-635-18

Manufacturer:	HMM Diagnostics GmbH Friedrichstrasse 89, 69221 Dossenheim Germany																				
Activity and product category:	Manufacture and final inspection; blood lancets, noninvasive blood pressure monitors. GMDN code: 61578 (lancet), 45617 (blood pressure monitor)																				
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</td> <td>• smartLAB</td> <td></td> <td>Ila</td> </tr> <tr> <td>- Blood pressure monitor</td> <td>• smartLAB</td> <td>• easy nG</td> <td>Ila</td> </tr> <tr> <td></td> <td></td> <td>• pressure</td> <td>Ila</td> </tr> <tr> <td></td> <td></td> <td>• pressure W</td> <td>Ila</td> </tr> </tbody> </table>	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	<i>Class</i>	- Blood lancet	• smartLAB		Ila	- Blood pressure monitor	• smartLAB	• easy nG	Ila			• pressure	Ila			• pressure W	Ila
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- Blood lancet	• smartLAB		Ila																		
- Blood pressure monitor	• smartLAB	• easy nG	Ila																		
		• pressure	Ila																		
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Date:	Valid from: 22 nd March 2018																				
	  Olli Kakkonen  Mikko Soikkeli																				

This attachment 1 supersedes the previous attachment 1 signed 20th April 2017

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

VTT EXPERT SERVICES LTD

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