



STATEMENT

Marz, 1st of March, 2021

Subject: Implementation of the Regulation of the European Parliament on Medical Devices: MDR (EU) 2017/745 und IVDR (EU) 2017/746

To whom it may concern

We, the MED TRUST Handelsges.m.b.H. company, with headquarter in Gewerbepark 10, 7221 Marz, Austria, are manufacturer of medical products for diabetics under the registered trademark "Wellion®".

All products listed in Appendix I of this statement have been certified under the European Medical Device Directive 93/42 / EEC and In-Vitro Diagnostics Directive 98/79 / EC and remain binding until the expiry of the validity of the respective EC certificate despite the entry into force of the MDR (EU) Directive 2017/745 (May 26th, 2021) and IVDR (EU) Directive 2017/746 (May 26th, 2022).

Medical devices:	EC Certificate	HD 60153015 0001	Valid until 2024-05-04
	EC Certificate	DD 60141729 0001	Valid until 2024-05-26
In vitro Diagnostic devices:	EC-Certificate	HL 60146513 0001	Valid until 2024-05-26

Wellion® products that are registered can remain on the market due to the validity of the product EC certificates.

In the near future, declarations of conformity for registered products can be viewed on the MED TRUST website.

The following activities have already been implemented in accordance to the requirements of Regulation (EU) 2017/745 and 2017/746:

- Registration in EUDAMED, single registration number (SRN):

Manufacturer	AT-MF-000000311
Importer	AT-IM- 000000335
- Responsible person according to Article 15 (PRRC) has been appointed,
- QM system adjustment for the processes: risk management, market surveillance, post-market surveillance and vigilance.

We, the MED TRUST company, have already applied for the audit according to Regulation (EU) 2017/745 (MDR) by our notified body TÜV Rheinland, Germany,

New medical products from MED TRUST will be legally registered according to MDR from May 26th, 2021 and IVDR from May 26th, 2022.

Please do not hesitate to contact us if you any further question occur.

Best regards



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THE MEDICAL SERVICES COMPANY

Annex I

Registered products of MED TRUST Handelsges.m.b.H.

Medical devices
Wellion® Lancets
Wellion® Safety Lancets
Wellion® MEDFINE plus Penneedles
Wellion® PROTECT PRO SAFETY PENNEEDLES
Wellion® MEDFINE Insulin Syringes
Wellion® EASY Infusionsset
Wellion® FAST steel Infusionsset
Wellion® Reservoir
Wellion® WAVE
Wellion® WAVE professional

In vitro Diagnostic devices
Wellion® Blood Glucose Meters
Wellion® Blood Glucose- and Cholesterol Meters
Wellion® Blood Glucose- and Ketone Meters
Wellion® Blood Glucose- ,Cholesterol and Uric Acid Meters
Wellion® Glucose Control Solutions and Test Strips
Wellion® Cholesterol Control Solutions and Test Strips
Wellion® Uric Acid Control Solutions and Test Strips
Wellion® Ketone Control Solutions and Test Strips