beurer
Gesundheit und Wohlbefinden

Confirmation regarding the MDR and IVDR

Förderndes Mitglied der Deutschen Hochdruckliga

Förderndes Mitglied der Deutschen Diabetes Stiftung

Ulm, 13.09.2023

Dear Sir/Madam,

We would hereby like to inform you about the current status of MDR approval (Medical Device Regulation EU 2017/745) and IVDR approval (In-Vitro Diagnostic Regulation 2017/746) at Beurer.

In particular, this also covers the (currently published and therefore applicable) proposal from the EU Commission to postpone the MDR.

All selected **MDR Class IIa** products from our company will have been changed over to the MDR well before the deadline of 31/12/2028.

MDR approvals are already available for various Class IIa products. The necessary production steps are currently being prepared.

The following products are already approved (changes between the last confirmation and now are marked in **red**):
Blood Pressure Monitors BM 28, BM 45, BM 54, **BM 53**
Pulse Oximeter PO 60, **PO 30**
Massager FM 150
Insect Bite Healer BR 60
Thermometers FT 65, FT 79, FT 85
Hearing Amplifiers HA 20
Infrared lamp IL 35, IL 60
Nebulizer IH 60

We already have the MDR certificates in these product categories, clearing the way for us to change over further existing and new products.

Starting on 26/05/2021, all **Class 1 products** were certified under the MDR in good time and registered in line with the options available to us at that time (German Institute for Medical Documentation and Information (DIMDI) and/or EUDAMED). The following Class 1 products are currently registered:

Lice Comb HT 15
Manual Breast Pump BY 15
Masks MM 10, MM 15
Lancing device
LifePad RH 112

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Another important change is that all MDD products that have already been placed on the market or will be placed on the market by 31/12/2028 (e.g. retail inventory), may be passed on to end customers without any further deadlines applying. The “provision date” therefore no longer applies.

Our notified body will issue a confirmation letter regarding the continued validity of the MDD certificates.

For our selected **in-vitro diagnostic products**, e.g. blood glucose monitors, the CE declarations of conformity will have been promptly changed over under the IVDR (EU 2017/746) by the time the IVD certificates expire on 17 December 2024. The EU committees are currently discussing whether to introduce a postponement similar to the MDR here, too.

In any case, the same arrangement as mentioned above applies here again: All IVD products that have already been placed on the market or will be placed on the market by the aforementioned deadline (e.g. retail inventory), may be passed on to end customers without any further deadlines applying.

The CE declarations of conformity under the MDR/IVDR will be issued and made available to you based on the progress we make with the approval steps.
The CE declarations of conformity under the MDD/IVD will remain valid until then.

The information above relates to the current status of the legislation and its implementation.

If you have any further questions about the MDR/IVDR, please do not hesitate to contact us at the following e-mail address:
mdr-info@beurer.de

Kind regards,

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Director QM/ Regulatory Affairs
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