



Export and Production
- since 1949 -

Heinz Herenz Medizinalbedarf GmbH • Rudorffweg 10 • 21031 Hamburg, Germany

Self-declaration of the company Heinz Herenz Hamburg concerning the amendments to the European Regulations (EU) 2017/745 MDR and (EU) 2017/746 IVDR

To whom it may concern:

Heinz Herenz Medizinalbedarf GmbH is active in the field of medical devices for 75 years and since 1996 we are certified according to DIN EN ISO 13485 in the respective valid version. Subsequently our company has also implemented a comprehensive quality management system. This system e.g. defines continuous traceability and controls.

On March 20th, 2023, Regulation (EU) 2023/607 came into force with the adaptation of the transitional provisions for certain medical devices (MD) and in vitro diagnostic medical devices (IVD). This means that MD/IVDs that are still compliant with Directives 93/42/EEC and 98/79/EC may be placed on the market or put into service beyond May 2024. The regulation also removes the sell-off period for IVDs.

Our certificates were issued by MEDCERT (0482) after May 25th, 2017 and were still valid on May 26th, 2021. The certificates have not been withdrawn. Our certificates are therefore valid until December 31st, 2028 and the products that we placed on the market before our certificates expired will be sold as long as stock lasts.

For our product groups "Bacterial sample collecting sets, Scalpel blades, Single use scalpels and Stitch cutter" we will continue to act as a manufacturer. Therefore, for these products, until the complete transition to the MDR, December 31st, 2028 is the validity date for our certificates in accordance with Directive 93/42/EEC.

We act as importer / distributor for many other products. Of course, the requirements of Articles 13 and 14 of the MDR/IVDR will be implemented in the existing QM system. The usual high quality of the medical products will not change. The layout of the products will also remain largely unchanged.

Patient safety will of course continue to be our highest priority. We will observe also in the future all necessary legal and regulatory requirements and provisions. This includes a review and verification procedure for all new products before introduction to the market to ensure that they do fulfil completely the requirements of the MDR. If we believe or have reason to believe that a product does not meet the requirements of the MDR/IVDR, we will act accordingly.

We are aware of our responsibility as a manufacturer, importer and distributor of medical devices in accordance with MDR/IVDR.

Hamburg, April 2024



Mr. Dieter Cyll (Managing Director)

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Self-declaration MDR deadlines

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Bank details

Postbank Hamburg
Hamburger Sparkasse
-Deutsche Bank EUR
Deutsche Bank USD

IBAN

DE97 2001 0020 0684 6462 00
DE87 2005 0550 1085 2430 02
DE82 2007 0000 0550 0251 00
DE82 2007 0000 0550 0251 00

BIC

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