EC DECLARATION OF CONFORMITY

According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III

We confirm that all In-Vitro Diagnostic medical devices

manufactured by ulti med Products (Deutschland) GmbH meet the essential requirements of Directive 98/79/EC Annex I and are suitable for the intended use.
All devices except pregnancy self-tests are classified as "other IVD products".

Laws, rules and standards, applied

Directive 98/79/EC	of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
EN ISO 13485:2016/AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: general requirements
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-2: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostics reagents for professional use
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641: 2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagent

Ahrensburg 2022-05-25

ulti med Products (Deutschland) GmbH

CEO

ulti med Products (Deutschland) GmbH
Reeshoop 1, D-22926 Ahrensburg (Germany)
##49 (0) 4102 - 80090; Fax ##49 (0) 4102 - 50082
Tax-ID-No. DE 154 23 11 80, Handelsregister Ahrensburg: HRB 3562
Geschäftsführer: Matthias W. Engel