EC DECLARATION OF CONFORMITY

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

We confirm that In-Vitro Diagnostic medical devices:

Product:	COVID-19 Antigen Saliva Test	Lot number:	xxxx
Product ID:	012G521	Exp.:	20xx-xx
		Quantity:	xxxx

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. The EC Declaration of Conformity is subject to the manufacture's responsibility.

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 14971:2012	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 diagnostic 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 2021-01-15

ulti med Products (Deutschland) GmbH

CEO

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