

CE Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

We,
Atlas Medical

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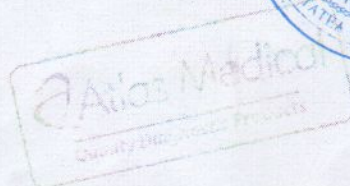
Declare our responsibility that the following product:

See Attached list

- Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
- This product is produced under Atlas quality system (ISO13485:2016) issued by Lloyd's Register Quality Assurance.
- Comply with the essential requirements of following standards (EN 18113-1, -2,-4:2011, EN ISO 15223:2016 , EN ISO 23640:2015, EN ISO 14971:2012, ISO 2859/1:1999, EN ISO 13612:2002, EN ISO 13641:2002.

And
Intended for In-Vitro Professional use only

Manufacturer
Atlas Medical
Ludwig-Erhard-Ring 3
D-15827 Blankenfelde-Mahlow



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