Declaration of Conformity/Konformitätserklärung

We/wir,

AB Diagnostic Systems GmbH, Sportfliegerstrasse 4, 12487 Berlin, Germany

declare on our own responsibility that the medical device/erklären in alleiniger Verantwortung, dass das Medizinprodukt

DC.001 abia DT

with indended use/mit der Zweckbestimmung

Disposable non-sterile conductive tips for use on robotic systems

in the following product variants/in folgenden Produktvarianten		**Batch number/Chargennummer**
DC.001.01.2	abia DT, 300µl	-
DC.001.11.2	abia DT, 1100 µl	-

meets all applicable requirements of the Council Directive 98/79/EC./allen anwendbaren Anforderungen der Richtlinie 98/79/EG entspricht.

Notified body/Benannte Stelle

not applicable

Conformity assessment procedure/Konformitätsbewertungsverfahren

Annex III excl. Point 6 of the Directive 98/79/EC

Certificate(s)/Ausgestellte Prüfbescheinigung(en)

not applicable

Used harmonised standards, CTS/Angewandte harmonisierte Normen, GTS

EC 1272/2008	Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)

Berlin, 2019-10-10

Place, Date

Philipp Roth, General Manager

B09.720.01/2

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