DECLARATION OF CONFORMITY

Name of manufacturer Address	**altona Diagnostics GmbH** **Mörkenstr. 12** **22767 Hamburg** **Germany**
Single registration number (SRN)	**DE-MF-000018379**

We declare on our sole responsibility that the medical device

Trade name	**FlexStar® (RT-)PCR Amplification Mix 1.5**
Product code	**FS0011515**
Basic UDI-DI	**42504531FS0011515T8**
Risk class	**A**
Intended Use	**The FlexStar® (RT-)PCR Amplification Mix 1.5 is an enzyme mix for *in vitro* diagnostic purposes. It is intended to be used for the real-time PCR based amplification and detection of nucleic acids (DNA and RNA) derived from human specimens.** **The FlexStar® (RT-)PCR Amplification Mix 1.5 is intended for use by professional users trained in molecular biological techniques and *in vitro* diagnostic procedures.**

is in conformity with all applicable requirements of Regulation (EU) 2017/746.

Common specifications used	**Not applicable**
Name of the notified body	**Not applicable**
Identification number	**Not applicable**
Conformity assessment procedure	**Regulation (EU) 2017/746, Annex II & III**
Reference number of the certificate	**Not applicable**

Hamburg, 01.03.2024

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Place, date

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Dr. Ulrich Spengler
Managing Director

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