

## DECLARATION OF CONFORMITY

Name of manufacturer **altona Diagnostics GmbH**  
 Address **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 **FS0011543**  
 Basic UDI-DI **42504531FS0011543TD**  
 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