altona DIAGNOSTICS

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	**ExtraStar® Purification Kit 2.0**
Product code	**5012045**
Basic UDI-DI	**4250453150120455Z**
Risk class	**A**
Intended Use	**The ExtraStar Purification Kit 2.0 uses magnetic particle technology and is intended to be used for the automated isolation and purification of nucleic acids from human respiratory swab specimens for *in vitro* diagnostic purposes.** **The product is designed for use with the KingFisher™ Flex Purification System (ThermoFisher Scientific) and altona Diagnostics kits and reagents specified for use with the ExtraStar® Purification Kit 2.0.** **The ExtraStar Purification Kit 2.0 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 Identification number	**Not applicable** **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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