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	**AltoStar® Purification Kit 1.5**
Product code	**PK15-46**
Basic UDI-DI	**42504531PK15-46WM**
Risk class	**A**
Intended Use	**The AltoStar Purification Kit 1.5 uses magnetic particle technology and is intended to be used for the automated isolation and purification of nucleic acids from specified human specimens for *in vitro* diagnostic purposes.** **The product is designed for use with the AltoStar Automation System AM16, the AltoStar Internal Control 1.5 and altona Diagnostics kits and reagents specified for use with the AltoStar Purification Kit 1.5.** **The AltoStar Purification Kit 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 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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