

## 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 **AltoStar® Internal Control 1.5**  
Product code **IC15-46**  
Basic UDI-DI **42504531IC15-46PN**  
Risk class **B**  
Intended Use **The AltoStar® Internal Control 1.5 is intended to be used as a nucleic acid purification, amplification and detection control for *in vitro* diagnostic purposes. It is designed for use with the AltoStar® Purification Kit 1.5 and altona Diagnostics kits and reagents specified for use with the AltoStar® Internal Control 1.5. The AltoStar® Internal Control 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 **mdc medical device certification GmbH**  
Identification number **0483**

Conformity assessment procedure **Regulation (EU) 2017/746, Annex IX**

Reference number of the certificate **D1267700040**

Hamburg,  
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Place, date

15/05/2025



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Dr. Sönke Friedrichsen  
Managing Director