

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® HAV RT-PCR Kit 1.5**
Product code **AS0241543**
Basic UDI-DI **42504531AS0241543RM**
Risk class **C**
Intended Use **The AltoStar® HAV RT-PCR Kit 1.5 is an *in vitro* diagnostic test, based on real-time PCR technology, for the qualitative detection of hepatitis A virus (HAV) specific RNA (genotypes I – III) in human EDTA and citrate plasma. It is intended to be used as an aid for diagnosis of HAV infection.**
The results generated with the AltoStar® HAV RT-PCR Kit 1.5 have to be interpreted in conjunction with other clinical and laboratory findings.
The AltoStar® HAV RT-PCR 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 **mdc medical device certification GmbH**
Identification number **0483**

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

Reference number of the certificate **D1267700043 and D1267700046**

Hamburg, 26.02.2026

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Place, date



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Hans Kuhn
Managing Director