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® Adenovirus PCR Kit 1.5**
Product code	**AS0301543**
Basic UDI-DI	**42504531AS0301543QN**
Risk class	**C**
Intended Use	**The AltoStar® Adenovirus PCR Kit 1.5 is an *in vitro* diagnostic test, based on real-time PCR technology, for the detection and quantification of human adenovirus (HAdV) specific DNA in human EDTA and citrate plasma and human EDTA and citrate whole blood. It is intended to be used as an aid for diagnosis of HAdV infection and for the monitoring of the HAdV load in individuals with HAdV infection. The results generated with the AltoStar® Adenovirus PCR Kit 1.5 have to be interpreted in conjunction with other clinical and laboratory findings. The AltoStar® Adenovirus 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 Identification number	**mdc medical device certification GmbH** **0483**
Conformity assessment procedure	**Regulation (EU) 2017/746, Annex IX**
Reference number of the certificate	**D1267700051**

Hamburg, 04.09.2026

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Place, date

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Dr. Sönke Friedrichsen
Managing Director

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