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® Parvovirus B19 PCR Kit 1.5**
Product code	**AS0101543**
Basic UDI-DI	**42504531AS0101543PU**
Risk class	**C**
Intended Use	**The AltoStar® Parvovirus B19 PCR Kit 1.5 is an *in vitro* diagnostic test, based on real-time PCR technology, for the detection and quantification of parvovirus B19 specific DNA in human EDTA and citrate plasma. It is intended to be used as an aid for diagnosis of parvovirus B19 infection and for monitoring of the parvovirus B19 load in individuals with parvovirus B19 infection.** **The results generated with the AltoStar® Parvovirus B19 PCR Kit 1.5 have to be interpreted in conjunction with other clinical and laboratory findings.** **The AltoStar® Parvovirus B19 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	**D1267700039**

Hamburg, 07.11.2024
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Place, date

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Dr. Sönke Friedrichsen
Managing Director

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