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® *alpha* Herpesvirus PCR Kit 1.5**
Product code	**AS0081543**
Basic UDI-DI	**42504531AS0081543S7**
Risk class	**C**
Intended Use	**The AltoStar® *alpha* Herpesvirus PCR Kit 1.5 is an *in vitro* diagnostic test, based on real-time PCR technology, for the qualitative detection and differentiation of herpes simplex virus 1 (HSV-1), herpes simplex virus 2 (HSV-2) and varicella-zoster virus (VZV) specific DNA in human cutaneous and mucocutaneous swab specimens collected in transport medium. It is intended to be used as an aid for diagnosis of HSV-1, HSV-2 and VZV infection. The results generated with the AltoStar® *alpha* Herpesvirus PCR Kit 1.5 have to be interpreted in conjunction with other clinical and laboratory findings. The AltoStar® *alpha* Herpesvirus 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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Managing Director

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