

Manufacturer's Declaration of Conformity for dedicated real-time PCR kits

altona Diagnostics GmbH has applied for certification of the following products according to Regulation (EU) 2017/746 ("IVDR"):

Product name	Product code	Certificate no.
AltoStar® CMV PCR Kit 1.5	AS0021543	D1267700031*
AltoStar® HBV PCR Kit 1.5	AS0201513	D1267700031*; D1267700033**
AltoStar® HCV RT-PCR Kit 1.5	AS0211513	D1267700031*; D1267700034**
AltoStar® HIV RT-PCR Kit 1.5	AS0221513	D1267700031*; D1267700032**

* EC Certificate as evidence of a quality management system in compliance with the requirements of European Directive 98/79/EC

** Product specific EC Design Examination Certificate in compliance with European Directive 98/79/EC

Therefore, these products as well as the RealStar® CMV PCR Kit 1.0 (Product no. 021013) are further permitted to be distributed as CE-marked IVD devices in the European Union, although the respective EC Certificates (see table above) issued as per European Directive 98/79/EC ("IVDD") by our Notified Body have expired.

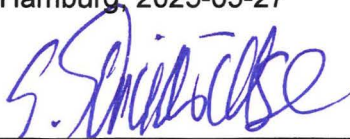
Despite the expiration of the Declarations of Conformity of all aforementioned products, compliance with the requirements of the IVDD will be maintained.

The issuance of a current Free Sales Certificate by the competent authority confirms the permission to distribute the products as CE-marked IVD devices within the European Union.

Signed for and on behalf of the manufacturer:

altona Diagnostics GmbH

Hamburg, 2025-05-27



Dr. Sönke Friedrichsen
General Management