EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith grants

altona Diagnostics GmbH Mörkenstraße 12 22767 Hamburg Germany

for the scope

AltoStar[®] HIV RT-PCR Kit 1.5 (REF AS0221513)

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven that the design meets the requirements according to

Annex IV – Section 4 of the Council Directive 98/79/EC

of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

This certificate is only valid in connection with a valid mdc certificate according to Annex IV – excluding section 4 and 6 for the above mentioned products.

Valid from Valid until Registration no. Report no. Stuttgart 2022-05-13 2025-05-26 D1267700032 P21-02058-223534 2022-05-13

Head of Certification Body





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