3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. 2024-IVDR/QS-003

Meril Diagnostics Pvt. Ltd.
Second Floor, D1 - D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396 191, Gujarat, India
SRN No.: IN-MF-000028158
Name of the Authorized representative:
Obelis s.a.; Bd., General Wahis 53, 1030, Brussels, Belgium
SRN No.: BE-AR-000000106

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended confirms, that quality management system of in vitro diagnostic medical device:

HIVFIND Whole Blood HIV 1/2 antibody detection self test
Trade Name: HIVFIND
Intended purpose: see Annex II
IVD MD class D
(detailed list is stated in the annex(es) if applicable)

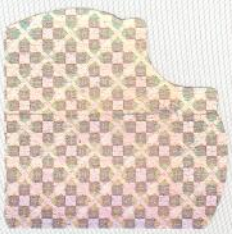
meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices as amended.

Conditions for or limitations to the validity of the certificate: **In vitro diagnostic medical device certified under the IVDR in the absence of an EURL. On sample or batch testing, NB2265 and manufacturer should follow the EURL-related provisions of Section 4.12 of Annex IX from the time that the EURL becomes operational.**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the above mentioned in vitro diagnostic medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the above mentioned in vitro diagnostic medical device is stated in the IVD MD Technical Documentation Assessment Report No. IVDR012_2023 from 17.04.2024, IVD MD Performance Evaluation Assessment Report No. IVDR012_2023 from 19.04.2024 and IVD MD Audit Report No. SK-0738-23 from 7.9.2023. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the above mentioned in vitro diagnostic medical device. For the placing on the market of the IVD MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/746 on in vitro diagnostic medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **26.04.2024**
Valid until: **26.04.2029**
First issue: **26.04.2024**
Revision: **00**
History: **See Annex III**

In Bratislava, Slovakia, 26.04.2024

3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265