



CERTIFICATE

EC Certificate No. 1434-IVDD-394/2020
Full Quality Assurance System

Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Premier Medical Corporation Private Limited
A1-302, GIDC, Sarigam 396155, Dist. Valsad,
Gujarat, INDIA

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

First Response® HBsAg Card Test
Ref: PI10FRC05CE, PI10FRC10CE, PI10FRC25CE, PI10FRC30CE

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 26.10.2020 to 27.05.2024

The date of issue of the Certificate: 26.10.2020



Issued under the Contract No. **MD-121/2019**
Application No: **185/2017**
Certificate bears the qualified signature.
Warsaw, 26.10.2020
Module **H7**

Vice-President



POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

KW.MV.2024.0200

Warsaw, 05.04.2024

To Whom It May Concern,

Polish Centre for Testing and Certification informs about the change introduced to the EC Certificates no. **1434-IVDD-393/2020** and **1434-IVDD-394/2020** issued for Premier Medical Corporation Private Limited, A1-302, GIDC, Sarigam 396155, Dist. Valsad, Gujarat, India, which results from the five-year certification period in accordance with Art. 9 section 10 of the Directive 98/79/EC, in force at the time the certificate was issued.

The EC Certificate validity date has been updated to **28 September 2025**.

Implementation of the change does not represent a significant change in design or intended purpose under Regulation (EU) 2017/746 Article 110(3) and the related IVDD Certificates no. 1434-IVDD-393/2020 and 1434-IVDD-394/2020 issued 26 October 2020 remains valid until its expiry date or 26 May 2025, whichever comes first.

Yours Sincerely,

**Head of Medical Device
Certification Department**



CERTIFICATION.
TESTING.
TRAINING.

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NIP 9512063356
REGON 015276609
KRS 0000144813

Initial capital
16.000.000 PLN
(fully paid)

Bank account: Bank Pekao S.A.
nr 90 1240 6003 1111 0000 4946 7594

The company registered in the District Court for
the Capital City of Warsaw, XIIIth Commercial Division