



# CERTIFICATE

**EC Certificate No. 1434-IVDD-396/2020**  
**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® HCV Card Test**  
Ref: PI03FRC05CE, PI03FRC10CE, PI03FRC25CE, PI03FRC30CE

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: **186/2017**  
Certificate bears the qualified signature.  
Warsaw, 29.09.2020  
Module **H7**

**Vice-President**



POLISH CENTRE FOR  
TESTING AND CERTIFICATION  
[www.pcbc.gov.pl](http://www.pcbc.gov.pl)

KW.MV.2024.0201

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-395/2020** and **1434-IVDD-396/2020** 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-395/2020 and 1434-IVDD-396/2020 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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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