



# CERTIFICATE

**EC Certificate No. 1434-IVDD-392/2020**  
**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® HIV 1-2.0 Card Test (Version 2.0)**  
**Ref: PI05FRC05CE, PI05FRC10CE, PI05FRC25CE, PI05FRC30CE**

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: **184/2017**  
Certificate bears the qualified signature.  
Warsaw, 26.10.2020  
Module **H7**

**Vice-President**