



# CERTIFICATE

**EC Certificate No. 1434-IVDD-393/2020**

**EC Design-examination**

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

Polish Centre for Testing and Certification certifies  
that manufactured by:

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

i.e. *in vitro* diagnostic medical devices  
List A

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

in terms of design documentation, comply with requirements  
of Annex IV (Section 4) 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 H6

**Vice-President**