



Premier Medical Corporation Private Limited

Unit-I

32-35, Shree Ganesh Indl. Estate, Kachigam,
Nani Daman, Daman - 396 215, (U.T.) INDIA

Unit-II

A1-302, GIDC, Sarigam 396155. Dist. Valsad,
Gujarat, INDIA • Tel.: +91 260 2780112 / 113

EC Declaration of Conformity

IVDD 98/79/EC

Reference No: PMC/QA/21/035

Doc No.: DOC/PI10FRC (Rev. AB)

Manufacturer Name:

Premier Medical Corporation Private Limited

Manufacturer Address:

Premier Medical Corporation Private Limited
A1-302, GIDC, Sarigam – 396155. Dist. Valsad, Gujarat, India
Obelis S.A.

European Representative Name:

European Representative Address:

Bd. General Wahis, 531030 Brussels, Belgium

Product Name:

First Response® HBsAg Card Test

GMDN Codes :

48322

Classification :

List A

Catalogue No.:

PI10FRC05CE, PI10FRC10CE, PI10FRC25CE, PI10FRC30CE

Conformity Assessment Route:

Annexure IV Applied (IVD 98/79/EC)
Full Quality Assurance (EN ISO 13485:2016) audit by;
Polish Center for Testing and Certification., Number: 1434
23A Klobucka Street, 02-699 Warsaw

Standard Applied:

ISO 13485:2016, EN ISO 18113-2:2011,
EN ISO 13485:2016, EN ISO 15223-1:2016,
EN ISO 14971:2012, EN ISO 23640:2015,
EN ISO 18113-1:2011, BS EN 13612:2002

Notified Body:

Polish Centre for Testing and Certification., Number: 1434
23A Klobucka Street, 02-699 Warsaw

EC Design Certificate No.

1434-IVDD-393/2020

Valid Until: 27/05/2024

EC Certificate Full Quality Assurance:

1434-IVDD-394/2020

Valid Until: 27/05/2024

We herewith declare that the above-mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation are retained under the premises of the manufacturer. Premier Medical Corporation Private Limited is exclusively responsible for the declaration of conformity.

On Behalf of Premier Medical Corporation Private Limited

Vikas Nakrani
2024-04-05

Mr. Vikas Nakrani

Sr. Manager-Quality Assurance & Regulatory Affairs

Place: Sarigam, Gujarat, India.

