PRECISION BIOSENSOR

EC Declaration of Conformity

In accordance with EC directives 98/79/EC (Annex III) relating to *In Vitro* Diagnostic Medical Devices

We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the requirements of the above EC Directive.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid.

Description of Product: The Exdia D-dimer 2 is a time resolved fluorescence immunoassay for the quantitative determination of D-dimer in human whole blood and plasma specimen with Exdia analyzer. The test is used as an aid in the diagnosis of Disseminated Intravascular Coagulation (DIC), or Venous Thromboembolism (VTE), which includes Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE). Cassette is sealed in pouch with desiccant, disposable sample dropper and provided with instructions for use.

Product Name	Fluorescence immunoassay
Brand Name	Exdia D-dimer 2
EDMA Description	D-dimer – RT & POC
EDMA code	13.02.70.03
Classification	Other IVD
European Authorized Representative	mdi Europa Langenhagener Str. 71, D-30855 Hannover-Langenhagen, Germany +49-511-3908 95313

■ **Relevant EC Directives:**

98/79/EC *In Vitro* Diagnostic Medical Devices (Annex III)

■ **Applied Standards:**

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

■ **Manufacturers Registered Name:** Precision Biosensor Inc.

■ **Manufacturers Registered Address:** 306, Techno 2-ro, Yuseong-gu, Daejeon, Korea, 34036

■ **Date: Mar 31, 2021**

CE

6 April 2021

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THE MEDICAL DEVICE SERVICE MANAGEMENT

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Hanshin Kim, CEO
Precision Biosensor Inc.