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 Device: Instrument to quantitate signal intensity of Immuno-chromatography Test by image analysis method

Product Name: Quantitative Image Analyzer

Model Name : Exdia TRF Plus

EDMA Description: Other POC Hardware + acc + cons + software

EDMA code: 21.07.11.09

Classification: Other IVD

European Authorized Representative:

- **Name: mdi Europa**
- **Address:** Langenhagener Str. 71 D-30855 Hannover-Langenhagen,Germany
- **Tel:** +49-511-3908 95313

Relevant EC Directives : 98/79/EC In Vitro Diagnostic Medical Devices (Annex III)

Applied Standards :

EN ISO 13485:2003, EN ISO 14971:2012, EN ISO 15223-1:2016, EN ISO18113-1:2011, EN ISO 18113-3:2011, EN 61326-1:2013, EN 61326-2-6:2006, EN 61010-1:2010, EN 61010-2-101:2002, EN 13612:2002, EN 62304:2006, EN 62366-1:2015

Manufacturers Registered Name: Precision Biosensor Inc.

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

Date: 2018/ 02/ 26

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mdi Europa
THE MEDICAL DEVICE EXPERTS

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