CO-DIAGNOSTICS INC.

# EC Declaration of Conformity

| Manufacturer | **Co-Diagnostics, Inc**<br>**2401 S Foothill Dr. Ste D**<br>**Salt Lake City, UT 84109 USA**<br>Phone: +1 (801) 438-1036<br>Email: info@codiagnostics.com<br>Website: www.codiagnostics.com |
|---|---|

We, Co-Diagnostics, Inc. declare with sole responsibility, that our product:

| EDMA Code | EDMA Description | Internal Product Name | Classification Rationale per IVDD |
|---|---|---|---|
| 15.04.40.90.00 | Other Virology - NA Reagents | Logix Smart™ Coronavirus disease 2019 (COVID-19) | Other IVD. Not listed in Annex II List A or B. |

meets the essential requirements of Council Directive 98/79/EC pertaining to in vitro diagnostics. Pathway of conformity per Annex III.
The product(s) identified above meet requirements of the IVDD by meeting the following standards

| Standard No. | Standard Description |
|---|---|
| EN ISO 13485:2016 | Medical Devices. Quality management systems. Requirements for Regulatory purposes. |
| DIN EN ISO 14971:2013 | Medical Devices – Application of risk management to medical devices |
| EN ISO 13612:2002 | Performance Evaluation of in vitro diagnostic medical devices |
| EN ISO 13612:2002/AC:2002 | Amendment to Performance evaluation of in vitro diagnostic reagents |
| EN ISO 15223-1:2016 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied. |
| EN ISO 23640:2015 | In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents |

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 1, § 2(g) of Directive 98/79/EEC.

Signed this day. . . . . Cecilia Hutchins . . . . . 20-Feb-2020 . . .

Cecilia Hutchins, Regulatory Affairs Liaison

Expiry Date:

mdi Europa use only!

The necessary pre-requisites for placing the CE mark on the above mentioned products and marketing them in all Member States of the European Union have thus been fulfilled.

Signed this day 24 February 2020

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mdiEuropa
THE MEDICAL DEVICE SERVICE-MANAGEMENT