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April 2020

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EC Declaration of Conformity

We,

Labcon, North America
3700 Lakeville Highway, Petaluma, California, USA 94954
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Declare with sole responsibility, that our product (s)

EDMA Class 24 09 Micro Biology Disposables as:

Pipet Tips (Pipette tips)
Centrifuge Tubes and (Micro) centrifuge tubes
Culture Tubes
Disposable Laboratory Plastics
PCR Disposables

EDMA Class 21 01 1001 CH Hardware and Assessories as:

POC Blood Dispenser
Blood Slide Prep Tool

Meet 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:

ISO 9001:2015 Quality Management Systems
ISO 14971:2007 Risk Assessment
EN980:2008 Symbols Used in Labeling Medical Devices
EN ISO 18113-1:2011 Labeling of In-Vitro Diagnostic Devices
EN ISO 18113-1:2011 ISO 15223-1:2007 Symbols to be used with In-Vitro Diagnostic Devices

Our authorized representative within the European community as explicitly defined in Article 1. § 2(g) of Directive 98/79 EEC is:

EC REP

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