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May 2022

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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:
Centrifuge Tubes and (Micro) centrifuge tubes
Culture Tubes
Disposable Laboratory Plastics
Specimen Containers

EDMA Class 21 01 1001 CH Hardware and Assessories as:
POC Blood Dispenser
Blood Slide Prep Tool

Meet the essential requirements of Regulation 2017/746 pertaining to in-vitro diagnostic medical devices. Class A.

The product(s) identified above meet requirements of the regulation 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 Regulation 2017/746 is:

EC REP

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