



April 2021

21

# EC Declaration of Conformity

We,

**Labcon, North America**

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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:

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21