# EC Declaration of Conformity

In accordance with EN ISO/IEC 17050-1:2010

We, **IVUS Medical ApS, Agern Alle 5A, 2970 Hørsholm, Denmark**, as Legal Manufacturer declare that:

**Products name:** **IVUS tube 10 ml**

**Product types:** **Tube for biological fluids10ml, individually packed**
**Item:** IV-2002

Is manufactured in accordance with the following Directives:

Regulation **(EU) 2017/746** of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

Conforms to the essential requirements of the In Vitro Diagnostics Directive and amending directives.
**Classification:** General IVD Medical Device, Class A
Conformity Assessment route: **(EU) 2017/746** Annex IV applied.

In addition, the following internally used standard applies:

EN ISO 13485:2016 Quality Management System requirements

I hereby declare that the equipment named above has been tested and found to comply with the relevant sections of the above referenced specifications. The unit complies with all essential requirements of the Directives.

Signed:

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Hans-Henrik Ulm
QA/QC Manager, IVUS Medical ApS
15-04-2025, Hørsholm, Denmark