



EC Declaration of Conformity

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

We, **IVUS Medical ApS, Frederiksborggade 15, 1360 Kbh. K, Denmark**, as Legal Manufacturer declare that:

Products name: IVUS Urine kit

Product types: Urine kit: beaker,
Vacuum tube U shape, 4 ml
Item: IV-1027

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:

Hans-Henrik Ulm
QA/QC Manager, IVUS Medical ApS
01-06-2026, Kbh. K, Denmark