cube dx
hybCell technology

IVDR Self Certification – Class A Declaration of Conformity

European Communities Council Regulation EU 2017/746 Concerning IVD Medical Devices

LINA

Cube Dx GmbH
Westbahnstraße 55
4300 St. Valentin/Austria
SRN: AT-MF-000013909
www.cubedx.com
UID: ATU 69753849

EU Declaration of Conformity

European Communities Council Regulation EU 2017/746

Concerning IVD Medical Devices

LINA

Manufacturer: **Cube Dx GmbH**
Westbahnstraße 55
4300 St. Valentin
Austria
SRN: AT-MF-000013909
www.cubedx.com
UID: ATU 69753849

We hereby declare that the following mentioned products meet the provisions of the Council Regulation EU 2017/746 covering medical devices. All documentation was checked and is retained on company premises. This declaration of conformity is issued under the sole responsibility of Cube Dx GmbH. The conformity assessment has been conducted by the manufacturer under its sole responsibility, in accordance with Article 48(10) of Regulation (EU) 2017/746.

Product data:

Product Name	***UDI-DI / REF***
LINA	09120127730152

The technical documentation for listed devices is prepared according to EU 2017/746 by Cube Dx GmbH. The devices listed in the table above are in vitro diagnostic (IVD) medical devices classified as class A according to Regulation (EU) 2017/746.

Basic UDI-DI:	912012773LINA8L
Classification:	Class A, Rule 5A *Rationale: Sample preparation Kits are considered as low risk products hence there is a low individual and public health risk.*
Conformity Assessment Procedure:	Conformity Assessment Route: Audit of technical documentation (EU) 2017/746 Annex II, III
GMDN Code:	58237

Cube Dx GmbH
Westbahnstraße 55
4300 St. Valentin/Austria
SRN: AT-MF-000013909
www.cubedx.com
UID: ATU 69753849

cube dx
hybCell technology

EMDN Code:	W02050106
Intended Purpose:	*LINA* is a sample preparation kit designed for manual preparation of (positive) blood cultures and bronchoalveolar lavages (BAL) for follow-up DNA testing of bacteria and fungi. The kit is a reagent that modulates the sample for the direct usage – without DNA extraction – for DNA based testing. The product is used in conjunction with DNA based tests, for example PCR tests or DNA sequencing, delivers qualitative results and aids the diagnosis of bacterial and/or fungal respiratory (BAL) or other infections (blood culture). The usage of the product is independent of patient's age, gender, genotype, or any demographic aspect. No specific patient group is excluded from testing. The attending physician decides if the sample-taking procedure is justifiable for any individual patient. The product is intended for professional use as part of comprehensive diagnostic workflows.

List of applicable standards:

Standards, directives and laws: Fundamentals	
Number	***Title***
REGULATION (EU) 2017/746	EU 2017/REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL from 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	Medical devices – Application of risk management to medical devices
ISO/TR 20416	Post-market surveillance for manufacturers
EN ISO 15223-1	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 20417	Medical devices — Information to be supplied by the manufacturer
EN 13641	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 23640	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

Cube Dx GmbH
Westbahnstraße 55
4300 St. Valentin/Austria
SRN: AT-MF-000013909
www.cubedx.com
UID: ATU 69753849

St. Valentin, 09.10.2025

Tanja Spenlingwimmer, MSc.	Christoph Reschreiter, Mag.	Bernhard Ronacher, Dr.
(PRRC, Cube Dx GmbH)	(CEO, CubeDx GmbH)	(CSO, CubeDx GmbH)