cube dx
hybCell technology

IVDR Self Certification – Class A Declaration of Conformity

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

GINA

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

cube dx
hybCell technology

EU Declaration of Conformity

European Communities Council Regulation EU 2017/746

Concerning IVD Medical Devices

GINA

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***
GINA 500 + DNA purification	09120127730145
GINA 500	09120127730244
GINA Lyse 200	09120127730664

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:	912012773GINA7H
Classification:	Class A, Rule 5A *Rationale: Kits for isolation and purification of nucleic acids from human specimens are listed as example for Rule 5A. 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

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

cube dx
hybCell technology

GMDN Code:	52521
EMDN Code:	W02050106
Intended Purpose:	The *GINA 500 + DNA Purification Kit* and its variant *GINA 500* are sample preparation and DNA/RNA extraction kits designed for manual or semi-automated sample preparation and extraction of microbial (bacterial/fungal) DNA/RNA from EDTA whole blood. The kits are a set of reagents that deplete human cells and DNA from EDTA whole blood samples and efficiently lyse microbial cells and purify their DNA. The products are used in conjunction with DNA-based tests, for example, PCR tests or DNA sequencing, to deliver qualitative results and aid in the diagnosis or the screening of suspected bacterial and/or fungal bloodstream infections. The usage of the products is independent of the 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 products are 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

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

cube dx
hybCell technology

EN ISO 23640	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents

St. Valentin, 12.08.2026

CE

Tanja Spenlingwimmer, MSc.
(PRRC, Cube Dx GmbH)

Christoph Reschreiter, Mag.
(CEO, CubeDx GmbH)

Bernhard Ronacher, Dr.
(CSO, CubeDx GmbH)