



IVDR Self Certification – Class A Declaration of Conformity

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

hyborg Dx RED2

EU Declaration of Conformity
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Concerning IVD Medical Devices
hyborg Dx RED2

Manufacturer: **Cube Dx GmbH**
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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
hyborg Dx RED2	09120127730015

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.

<u>Basic UDI-DI:</u>	912012773HDR-001XD
<u>Classification:</u>	Class A, Rule 5B <i>Rationale: Rule 5b applies to instruments specifically intended by the manufacturer for in vitro diagnostic procedures.</i>
<u>Conformity Assessment Procedure:</u>	Conformity Assessment Route: Audit of technical documentation (EU) 2017/746 Annex II, III
<u>GMDN Code:</u>	57851

Author	Tanja Spenlingwimmer	Version	V002
Approved by	Christoph Reschreiter	Date	09.10.2025

EMDN Code:	W02050201
Intended Purpose:	The hyborg Dx RED 2 is an automated, qualitative in vitro diagnostic (IVD) device designed to process and analyze microarray tests, conducted by using Cube Dx hybcell test cartridges. The device facilitates the detection and/or measurement of analytes based on the specific hybcell tests utilized. The hyborg Dx RED 2 is not limited to any particular analyte, as the range of analytes detectable depends solely on the selected hybcell tests, not the device itself. Depending on the hybcell tests used, the device is capable of performing various functions, such as screening, monitoring, diagnosis, diagnostic aid, therapy-accompanying diagnostic, prognosis, or prediction. The context in which diagnostic information is provided depends on the hybcell tests employed, and the device is not limited to any specific clinical or diagnostic context. The hyborg Dx RED 2 can deliver qualitative, semi-quantitative, or quantitative results, depending on the configuration of the processed hybcell tests. The device is suitable for processing a wide range of sample types and is not restricted to any specific sample material, target population, or medical condition. This device is exclusively intended for professional users in a clinical or laboratory setting.

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		
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EN ISO 23640	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
IEC 61010-2-010	Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-051	Safety requirements for electrical equipment for measurement, control and laboratory use Part 2: Particular requirements for mixing and stirring
IEC 61010-2-101	Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 60825-1	Safety of laser products - Part 1: Equipment classification and requirements
EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements Part 1: General requirements
EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

St. Valentin, 09.10.2025



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