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IVDR Self Certification – Class A Declaration of Conformity

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

Waste Bottle

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

Waste Bottle

Manufacturer: **Cube Dx GmbH**
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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***
Waste Bottle	09120127730046

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:	912012773HDR-004XK
Classification:	Class A, Rule 5A *Rationale: Products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, (…), intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination.*
Conformity Assessment Procedure:	Conformity Assessment Route: Audit of technical documentation (EU) 2017/746 Annex II, III

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GMDN Code:	62172
EMDN Code:	W02050285
Intended Purpose:	The Waste Bottle is an accessory intended for use with Cube Dx hyborg devices. It is designed to collect and safely contain waste fluids generated during the automated processing and analysis of microarray tests conducted with Cube Dx hybcell test cartridges. These waste fluids include used System Liquid, CS-Buffer, and reagents introduced into the hybcell cartridges during the testing process. The Waste Bottle ensures proper disposal of residual liquids and reagents, contributing to the safe and efficient operation of the hyborg. It plays a critical role in maintaining a contamination-free testing environment by securely managing waste materials, thus supporting the overall performance of the diagnostic system. The Waste Bottle is intended for use by professional users in clinical or laboratory settings, alongside the hyborg device, compatible with a wide range of analytes, sample matrices and diagnostic applications, supporting qualitative, semi-quantitative, or quantitative analyses, depending on the exact product configuration applied. This accessory is essential for ensuring the hygienic handling of waste and maintaining the integrity of diagnostic processes across various sample types and test functions.

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

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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

St. Valentin, 09.10.2025

CE

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