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IVDR Self Certification – Class A Declaration of Conformity

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

Buffers

Cube Dx GmbH
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UID: ATU 69753849

EU Declaration of Conformity

European Communities Council Regulation EU 2017/746

Concerning IVD Medical Devices

Buffers

Manufacturer:

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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***
CS-Buffer	09120127730503
System Liquid	09120127730022
PE-Buffer	09120127730138

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-005XM
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.*

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Conformity Assessment Procedure:	Conformity Assessment Route: Audit of technical documentation (EU) 2017/746 Annex II, III
GMDN Code:	58236
EMDN Code:	W02050285
Intended Purpose:	The System Liquid, CS-Buffer, and PE-Buffer are essential accessories for use with Cube Dx hyborg devices. These buffers support the operation of the hyborg by ensuring optimal performance during the automated processing and analysis of microarray tests performed using Cube Dx hybcell test cartridges. • The System Liquid facilitates the maintenance and fluidic operations of the hyborg, ensuring proper washing of the tubing after hybcell processing as well as removing any residual Buffer in the tubing to prevent any possible bacterial or fungal growth within the device, ensuring optimal performance and reliability of the device. • The CS-Buffer (or Compact Sequencing Buffer) provides a specific chemical environment necessary for the correct functioning of hybcell microarray assays conducted by the device, contributing to the stabilization and integrity of analytes during testing as well as enabling a homogenous distribution of the PCR amplicons across the surface of the hybcells. • The PE-Buffer (or Primer Extension Buffer) provides a specific chemical environment necessary for the correct functioning of hybcell microarray assays conducted by the device, contributing to the stabilization and integrity of analytes during testing as well as enabling a homogenous distribution of the PCR amplicons across the surface of the hybcells. All buffers are critical for the accurate detection and measurement of analytes, as they support the overall diagnostic process carried out by the hyborg, they are suitable for qualitative, semi-quantitative, or quantitative analyses, depending on the exact product configuration applied. These accessories are not limited to any particular analyte, sample matrix, or diagnostic function, as their use depends on the hybcell tests employed. The buffers are suitable for various diagnostic applications, such as screening,

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	diagnosis, monitoring, prognosis, prediction, and therapy-accompanying diagnostics. The System Liquid, CS-Buffer, and PE-Buffer are intended for professional users in clinical or laboratory settings, in conjunction with the hyborg, to facilitate the reliable and efficient analysis of a wide range of sample types and diagnostic contexts, they should not be used separately or with other diagnostic platforms.

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

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St. Valentin, 09.10.2025

CE

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