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# IVDR Self Certification – Class A Declaration of Conformity

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

## IPC

**Cube Dx GmbH**
Westbahnstraße 55
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UID: ATU 69753849

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# EU Declaration of Conformity

## European Communities Council Regulation EU 2017/746

## Concerning IVD Medical Devices

## IPC

**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*** |
|---|---|
| **IPC** | 09120127730169 |

*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:** | 912012773PathoxBK8 |
| **Classification:** | Class A, Rule 5A<br><br>*Rationale: Products for general laboratory use, accessories which possess no critical characteristics (…). Product for verification of DNA extraction of low risk sample preparation kits.* |
| **Conformity Assessment Procedure:** | Conformity Assessment Route: Audit of technical documentation (EU) 2017/746 Annex II, III |
| **GMDN Code:** | 66439 |

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| | |
|---|---|
| **EMDN Code:** | W0105080808 |
| **Intended Purpose:** | The IPC (Internal Process Control) is an in vitro diagnostic medical device intended for professional use only in a clinical laboratory setting as an aid to diagnosis. Its function is to serve as a qualitative internal process control to monitor the adequacy of DNA or RNA extraction. The IPC's specific DNA is introduced manually into the specimen (EDTA blood) and subsequently co-extracted. Its successful detection in follow-up analyses with Cube Dx products confirms that the extraction process worked adequately. |

**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<br>from 5 April 2017<br>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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