

# EU Declaration of Conformity, DoC

We:  
Manufacturer, company name: DEKO MedTech Oy (VAT Number: FI09587362)  
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Hereby declare that this DoC is issued under our sole responsibility and refers to the following object:

Apparatus model: **DEKO D32**  
Basic UDI-DI / EUDAMED DI: B-Deko-32ML  
Intended purpose: **Instrument washer-disinfector**

This object is in conformity with the following Union harmonized legislation:

**Medical Device Directive (93/42/EEC)**

**RoHs 2011/65/EU, The Restriction of Hazardous Substances Directive**

References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:

- **EN 61010-1:2001 (Ed2)** **Safety requirements for electrical equipment for measurement, control, and laboratory use, General requirements**
- **EN 61010-2-040:2005** **Particular requirements for ward disinfectors used in medical, pharmaceutical, veterinary and laboratory fields.**
- **EN 61326-1:2005** **Electrical equipment for measurement, control and laboratory use. EMC requirements.**
- **EN ISO 13485:2016** **Medical devices. Quality management systems. Requirements for regulatory purposes**
- **EN ISO 14971:2019** **Medical devices. Application of risk management to medical devices.**

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- IEC 62304:2015	Medical device software - Software life-cycle processes
- SFS-EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
- EN ISO 15883-1:2014	Washer-disinfectors, Part 1: General requirements, definitions and tests
- EN ISO 15883-2:2009	Washer-disinfectors, Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
- ISO/TS 15883-5:2005	Washer-disinfectors. Part 5: Test soils and methods for demonstrating cleaning efficacy
- EN 1717:2000	Protection against pollution of potable water in water installations and general requirements of devices to prevent pollution by backflow

Notified Body:



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Signed for and on behalf of

Place of issue: Naarajärvi, Finland  
Date of issue: 11<sup>th</sup> November, 2024

Tero Andersson  
Managing Director  
DEKO MedTech Oy