EU-Declaration of Conformity

Document No.	SRQ-QR-22-0023[1]
Manufacturer	**SmartResQ ApS** Lundevej 26 DK-5700 Svendborg
SRN	DK-MF-000030638
Product designation	CorPatch®
Basic UDI-DI	42700031103A11AM
Medical device risk classification	Class I

The manufacturer bears sole responsibility for issuing this EU declaration of conformity. This is to certify that the requirements listed in *Table 1* and, where appropriate, other relevant Union legislation requiring the issuance of an EU declaration of conformity have been fulfilled in relation to the device that is covered[2].

(EU) 2017/745	Medical devices (MDR)
(EU) 2021/2226	Electronic instructions for use of medical devices
(EU) 2012/19	Waste electrical and electronic equipment (WEEE)
(EU) 2011/65	Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
(EU) 1907/2006	Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
DIN EN 60601	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
DIN EN 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances
DIN EN 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
DIN EN 62304	Medical device software – Software life cycle processes
DIN ISO 14971	Medical devices – Application of risk management to medical devices
DIN ISO 13485	Medical devices Quality management systems - Requirements for regulatory purposes

Table 1: List of covered EU regulations and standards

CHE-Klingnau, November 15th, 2024

Andreas Hofmann
CEO SmartResQ ApS

[1] Rev. 3.0
[2] Ref SRQ-QR-22-0022