InnoCon Medical	CE	**EU Declaration of Conformity European Regulations**	Declaration of Conformity - UCon [en], 2026-09-22

Company Name and Address	InnoCon Medical ApS Lyngvej 1 DK-9000 Aalborg Denmark		
Single Registration Number (SRN)	DK-MF-000048039		
Product Name	UCon	Basic UDI-DI	57400407PATCHHF
Codes	EDMN: U070299		
	UMDNS: 16029 - Stimulators, Urinary; 17505 - Incontinence Control Units, Fecal; 17784 - Stimulators, Incontinence Management		
Photo/Image		Catalogue Number	90-00-0090
Radio Equipment Types	BLE (Bluetooth Low Energy 4.2) NFC (Near Field Communication (13.56MHz))		
Technical Documentation Revision	001		
Risk Classification	Class IIa, according to Annex VIII, chapter III, Rule 9		
Intended Purpose	UCon is a neurostimulator applying electrical stimulation to the dorsal genital nerve for patient operated treatment of the symptoms of overactive bladder and bowel dysfunction.		
Conformity Assessment Route	MDR Annex IX, Chapters I, III		

We herewith declare under our sole responsibility that the above-mentioned product meets the provisions of:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (RED).

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

Directive (EU) 2017/2102 of the European Parliament and of the Council of 15 November 2017 amending Directive 2011/65/EU (RoHS).

Standards Applied	EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 13485:2021, EN ISO 14155:2020, EN ISO 14971:2021, EN ISO 15223-1:2025, EN ISO 20417:2021, EN 60601-1:2024, EN 60601-1-2:2021, EN 60601-1-6:2021, EN 60601-1-11:2021, EN 60601-2-10:2024, IEC 62133-2:2021, EN 62304:2015, EN 62366-1:2020. EN 55011:2016/A2: 2021, ETSI EN 300-328 V2.2.2:2019, ETSI EN 300-330 v2.1.1: 2017, ETSI EN 300-440-1 V2.1.1:2017, ETSI EN 300-440-2 V3.1.0:2025. ETSI EN 301-489-1 v2.2.3:2019, ETSI EN 301-489-3 v2.3.2:2023, ETSI EN 301-489-17 v.3.2.6:2023.
Notified Body and Number	BSI The Netherlands, NB: 2797
CE Certificate Number	MDR 829107
Place, Date of Issue	Aalborg, 2026-09-22
Signature	Torsten Hvalsøe Torsten F. Hvalsøe / Director of Operations and Regulatory Affairs, PRRC / InnoCon Medical On behalf of InnoCon Medical ApS – CEO, Jesper Nielsen

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