HIDREX®

Declaration of Conformity

With reference to the original MDD Declaration of Conformity dated 25.05.2021 and the Confirmation Letter of the NB BerlinCert with reference number 26-002-S and taking into account the guideline MDCG 2021-25 Rev. 1 we declare under our sole responsibility that the specified products comply with the regulations given below.

Manufacturer	Hidrex GmbH Otto-Hahn-Str. 12 42579 Heiligenhaus Germany	
Single Registration Number (SRN)	DE-MF-000004959	
Basic UDI-DI	42505713HIPRO10H5	
Product(s)	Name	UDI-DI
	classicION	04250571301105
	comfortION	04250571301464
	conceptION	04250571301303
	connectION	04250571301204
Intended Purpose	The HIDREX tap water iontophoresis devices are intended for the treatment of hyperhidrosis on the hands, feet, face, neck, back and under the armpits. Any other use or use beyond this is considered improper and may result in hazardous effects.	
Risk class	IIa	
Directive(s) / Regulation(s)	- 93/42/EWG (MDD) - Article 120 of Regulation 2017/745 (MDR) - 2011/65/EU (RoHS)	
Applicable common specifications	None	
Notified Body	BerlinCert NB no. 0633	

Note: The devices are legacy devices in compliance with Regulation 2017/745 (MDR).

Valid since: 05.03.2025 **valid till: 31.12.2028**

On behalf of the Hidrex GmbH

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