

DECLARATION OF CONFORMITY

iWALKFree, Inc. located at 130 N. Marina Drive, Long Beach, California, 90803, USA hereby declares that the product:

PART NUMBER: HFC30303 (DESCRIPTION: iWALK3.0 Hands Free Crutch)

meets the standards listed below, and as a company has implemented and maintains a full quality assurance system which applies to the product at every stage from design, manufacture, to final controls, and meets the provisions of FDA regulation under 21.CFR.890, the MDR Regulation (EU) 2017/745, and the applied harmonized standards:

EN ISO 13485: Quality Management System

EN ISO 11334-1:2007: Assistive Products for Walking Manipulated by One Arm

EN ISO 12182:2012: Assistive Products for Persons with Disability

EN ISO 13287:2004 / ASTM TM144:1999: Safety, Protective & Occupational Footwear

EN ISO 4649:2010 / ASTM D5963:2015: Rubber, Determination of Abrasion Resistance

DEVICE REGISTRATION & CLASSIFICATION		
USA FDA	CLASS I (non-sterile)	per 21.CFR.890.3150 (IPR/Crutch: Listing E388060) per 21.CFR.890.3475 (IQI/Orthosis: Listing E338061)
HealthCanada	CLASS I (non-sterile)	per Rule 7(1) of <i>Risk-based Classification System (non-IVDDS) ver2015.06.12</i>
EU MDR	CLASS I (non-sterile)	per MDR (EU) 2017/745, CHAPTER III (CLASS RULES), Rule 1 <i>MDR Conformity Assessment Route: Annex II & Annex III</i> EMDN ID: 6864, Code: Y120399 (<i>WALKING DEVICES, ONE-HANDED OPERATION – OTHER</i>) EUDAMED Device Identification: UDI-DI 00.8600.0259.0813
GMDN		17631 Single Side Support Walking Frame (alternate) 31114 Forearm Support Crutch (alternate) 31115 Axillary Crutch

CORPORATE REGISTRATION		
USA FDA	IWALKFREE, INC	Registration Number: 301.339.6989 FEI Number: 301.339.6989 Initial Distributor/Importer: Yes
HealthCanada	Iwalkfree, Inc.	Company Id: 142054, License Number: 6914 Manufacturer: YES (Distribute & Import: YES)
EU MDR	iWALKFree, Inc [United States]	Manufacturer: US-MF-000.00.8192 Mandate: MD-US-NL-000.00.2358
	EU Authorized Representative: CEpartner4U	EUDAMED Actor ID: NL-AR-000.000.111 Address: Esdoornlaan 13, MAARN, Utrecht 3951 DB, Netherlands

Location: Long Beach, California, USA	Name / Title: Brad Hunter, President
Date: February 7 th , 2022	Signature: 

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The EU declaration of conformity is issued under the sole responsibility of the manufacturer