130 N. Marina Drive
Long Beach, California
90803, USA

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

Authorized Representative for EU:
CEpartner4U (SRN: NL-AR-000.000.111)
Esdoorniaan 13
3951 DB Maarn
The Netherlands
EU Registration (Farmatec | CIBG):
iWALKFree, Inc. – iWALK Hands Free Crutch (NL-CA002-41653)

DEVICE 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)
EU MDR	CLASS I (non-sterile)	per MDR, (EU) 2017/745, CHAPTER III (CLASS RULES), Rule 1 MDR Conformity Assessment Route: Annex II & Annex III

Location: Long Beach, California, USA	Name / Title: Brad Hunter, President
Date: June 3rd, 2021	Signature:

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IWALKFREE INCORPORATED CORPORATE SEAL CALIFORNIA

(01)860002590813
(99)iWalkFreeInc

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