

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
Stander, Inc.	2410 S. Heritage Drive, Logan Utah 84321	TBD, when Eudamed is
		implemented.

AUTHORIZED REPRESENTATIVE				
Name of Company	Address	SRN	Telephone/fax/email	
Emergo Europe	Prinsessegracht 20	NL-AR-000000116	+31.70.345.8570 - phone	
	2514 AP The Hague		+31.70.346.7299 - fax	
	The Netherlands		EmergoEurope@ul.com	

PRODUCT IDENTIFICATION				
Product Name	Product Code / (Number	Catalog	Basic UDI-DI	
Ambulatory Assist Device Family	See attached list in Appendix A of the Technical File.		Bed Rail: 897564000818MS Grab Bar: 897564000122LE Walker/Rollator: 897564000030L8 Tray Table: 897564000733MH	
Intended Purpose		Photo		
Stander, Inc. medical assist products are devices intended for use by disabled persons to provide minimal to moderate weight support while standing and walking.		See attached list in Appendix A of the Technical File.		

RISK CLASS FOR MEDICAL I	DEVICES
Device Classification	Common Specifications
Class _1	N/A, not currently issued.
Rule _1	

NOTIFIED BODY			
Name of Company	ID Number	Conformity Assessment Procedure	Certificate Reference(s)
N/A	N/A	N/A	N/A

Stander Inc, declares that the above-mentioned products meet the provision of the following EU legislation:

• MDR (EU) 2017/745

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	INCIDATE	KEVKES		• unam	SCOTE

TITLE: Project Eng. SIGNATURE:

PLACE: Logan, Utah USA

DATE: 06/04/2021

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