DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION (EU) 2017/745

Manufacturer:	**M.BIRLI – A. TSITOURAS O.E.**
Address:	12 AIGAIOU STR., N. SMIRNI, PC 17-121, ATHENS-GREECE TEL.: +30 210-9325445 FAX : +30 210-9325034 E-MAIL : info@step-on.net SITE: www.step-on.net
Device Classification: (As per MDR 2017/745)	Annex VIII, CHAPTER III, 4.1. Rule 1
Conformity Assessment Route: (As per MDR 2017/745)	Annexes II and III
Single Registration number (SRN)	GR-MF-000013450

We, **M. BIRLI – A. TSITOURAS O.E.** declare under our sole responsibility that the medical device stated below meets all provisions of the Medical Device Regulation (EU) 2017/745.

Product Name	Classification	Basic UDI-DI
STEP-ON AFO 100/LH	Class I	5200413200096JT
STEP-ON AFO 100/MH	Class I	5200413200133J8
STEP-ON AFO 200/DH	Class I	5200413200034J5
Step – On Ankle Hinge 100 / Bar /Cuff /Shoe support	Class I	5200413201666KP
Step – On Ankle Hinge 100 /Extension	Class I	5200413201796L5

This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745 with:

- Quality Management System certification to EN ISO 13485: 2016 under the supervision of LLOYD' S REGISTER, certificate number 10425894
- Availability of technical documentation per Annex II and Annex III of the Medical Device Regulation (EU) 2017/745

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List of Applicable Regulations and Standards

A/A	Regulation/ Standard Number	Year Of Issue	Regulation/ Standard Name
1.	**MDR: Regulation (EU) 2017/745**	**2017**	MDR: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
2.	**ISO 13485**	**2016**	Medical devices — Quality management systems — Requirements for regulatory purposes
3.	**ISO 14971**	**2019**	Medical devices - application of risk management to medical devices
4.	**ISO 22523**	**2006**	External limb prostheses and external orthoses- Requirements and test methods.
5.	**ISO 15223-1**	**2021**	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
6.	**Ministerial Decision ΔΥ8δ/1348**	**2004**	Principles and Guidelines for Good Distribution Practice of Medical Devices.

The above mentioned replaces any other declaration issued for the products.

Athens, February 7th , 2022

Andreas Tsitouras.

Company Administrator & Legal Representative

Producer:

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