

Certificate of Registration

In accordance with European Medical Device Regulation MDR (EU) 2017/745, we hereby declare that:

- An examination has been made of this organization’s Declaration of Conformity(s) and where appropriate Notified Body certification(s) exist.
- The EU Authorized Representative contract has been fulfilled.
- Device registrations for the medical devices mentioned within this certificate have duly been completed with an EU Competent Authority.


Therefore, these devices have met the requirements of the MDR (EU) 2017/745 and the CE mark may be applied to the products listed below.

Certificate:	Issue Date: June 10th, 2024
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Legal Manufacturer	EU Authorized Representative (EC REP)
PROTEOR USA, LLC 3 Morgan Irvine, CA 92618 USA	PROTEOR SAS 6 rue de la Redoute 21850 Saint-Apollinaire FRANCE
SRN: US-MF-000016997	SRN: FR-AR-000008332

Product Details, Names or Trade Names
Artificial Limbs & Prosthetic Devices

Competent Authority
ANSM - Site de Saint Denis 143/147, Boulevard Anatole France 93285 SAINT-DENIS CEDEX FRANCE

This certificate is issued by:	Authorized Signature:
PROTEOR SAS 6 rue de la Redoute 21850 Saint APOLLINAIRE France	

This certificate is subject to the organization maintaining their documentation in compliance with the directive stated in this certificate.

This certificate is for the exclusive use of PROTEOR USA, LLC and is provided pursuant of the European Authorized Representative agreement (Mandate) between PROTEOR SAS and PROTEOR USA, LLC. PROTEOR SAS responsibility and liability is limited to the terms and conditions of the European Medical Device Authorized Representative Mandate signed between both parties. Only PROTEOR USA, LLC and PROTEOR SAS are authorized to copy or distribute this certificate. This certificate remains valid until the expiry date has been reached or has been terminated by PROTEOR SAS.

Declaration of Conformity

for Everyday Prosthetic Foot

European Medical Device Regulation MDR (EU) 2017/745

The undersigned declares that the products described in this document meet the MDR (EU) 2017/745 provisions that apply to them and the CE Mark may be affixed.

General Product Name:	See Appendix II Description/Name list
Legal Manufacturer: (Name on Label)	PROTEOR USA, LLC 3 Morgan, Irvine, CA 92618 USA
Variants:	As per Appendix II (This document) - Product Listing/Schedule
Intended Use:	Lower Limb Prosthetic Device
MDR Classification:	Class I, in accordance with the rules set out in Annex VIII
Notified Body:	Not Applicable for Class I
EU Authorized Representative:	PROTEOR SAS 6 rue de la Redoute, 21850 Saint-Apollinaire FRANCE
MDR Assessment Route:	Self-certification by Medical Device Regulation Article 52, Section 7 Article 19: EU Declaration of Conformity Article 15: Person responsible for regulatory compliance



June 10th, 2024

Valery BARBOUR
Chief Operating Officer
Person responsible for Regulatory compliance

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
MDR (EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices
EN ISO 13485	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	Basic UDI
F15-00	Agilix	0888349AGILIXYV
F15-V2	Agilix EVAQ8	0888349AGILIXYV
KIT-00-1136U-00	AGILIX Heel Stiffening Bumper Kit	0888349AGILIXYV
F10-00	DynAdapt	0888349DYNADAPTGR
F10-V2	DynAdapt EVAQ8	0888349DYNADAPTGR
KIT-00-1137U-00	DYNADAPT Heel Stiffening Bumper Kit	0888349DYNADAPTGR
FS3-00	Highlander	0888349HIGHLANDER7R
FS3-V2-0	Highlander EVAQ8	0888349HIGHLANDER7R
KIT-00-1130U-00	HIGHLANDER Heel Stiffening Bumper Kit	0888349HIGHLANDER7R
FS3-H5	Highlander MAX	0888349HIGHLANDERMAXSJ
FS3-V2-1	Highlander EVAQ8 MAX	0888349HIGHLANDERMAXSJ
KIT-00-20200-00	Heavy Duty Kit, Titanium	0888349HIGHLANDERMAXSJ
FS1-00	Sierra	0888349SIERRA8F
FS1-V2	Sierra EVAQ8	0888349SIERRA8F
KIT-00-1135U-00	SIERRA Heel Stiffening Bumper Kit	0888349SIERRA8F
FS2-00	Pacifica	0888349PACIFICA8P
KIT-00-1134U-00	PACIFICA Heel Stiffening Bumper Kit	0888349PACIFICA8P
FS4-00	Pacifica LP	0888349PACIFICALP5D
KIT-00-1132U-00	PACIFICA LP Heel Stiffening Bumper Kit	0888349PACIFICALP5D
F20-S3	ShockWave	0888349SHOCKWAVE3Q
F20-V2	ShockWave EVAQ8	0888349SHOCKWAVE3Q
KIT-00-1146U-00	SHOCKWAVE Heel Stiffening Bumper Kit	0888349SHOCKWAVE3Q
F13-00	EXALTO	0888349EXALTO76
KIT-00-1148U-00	EXALTO Heel Stiffening Bumper Kit	0888349EXALTO76
RM3-00	Kinterra	0888349KINTERRA3ZB
RM3-V2	Kinterra EVAQ8	0888349KINTERRA3ZB
KIT-00-1147U-00	KINTERRA Heel Stiffening Bumper Kit	0888349KINTERRA3ZB