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: 24th March 2022**

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
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 Directive Annex IV Article 19: EU Declaration of Conformity Article 15: Person responsible for regulatory compliance

March 24th, 2022

Valery BARBOUR.

VP of Quality and Regulatory Affairs

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 Device
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	Basic UDI
F15	Agilix™ F15	0888349AGILIXYV
F10	DynAdapt™ F10	0888349DYNADAPTGR
FS3	Highlander™ FS3	0888349HIGHLANDER7R
FS3-HS	Highlander™ Max FS3-H5	0888349HIGHLANDERMAXSJ
FS1	Sierra™ FS1	0888349SIERRA8F
FS2	Pacifica™ FS2	0888349PACIFICA8P
FS4	Pacifica™ LP FS4	0888349PACIFICALP5D
ROM	Kinterra™ Foot/Ankle System ROM	0888349KINTERRALT
F20	Freedom ShockWave™	0888349SHOCKWAVE3Q

Version History

Version	Compiled by	Date	Description
1.0	Jean Chen	04/10/2017	First issue
2.0	Jean Chen	04/23/2019	2nd issue
3.0	Valery BARBOUR	12/14/2020	Change of ownership to PROTEOR USA, LLC Change of EU Rep to PROTEOR SAS Removal of: - Senator™ VS1 - Promenade™ VS2
4.0	Valery BARBOUR	05/25/2021	Compliance to EU MDR 2017/745
5.0	Valery BARBOUR	09/22/2021	Addition of Freedom ShockWave™
6.0	Valery BARBOUR	03/24/2022	Addition of EC REP and manufacturer SRNs