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: July 23rd, 2024**

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 Accessory

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:	Accessory for 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

July 23rd, 2024

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 Number	Part Description	Basic UDI-DI
ACC-00-10300-00	Tool, Foot Shell Removal	0888349ACCESSORIESTP
ACC-00-12500-00	TubeClamp, 30mm, FemalePyramid	0888349ACCESSORIESTP
ACC-00-12600-00	TUBE CLAMP,30MM,MALE PYRAMID(100kg-TITANE)	0888349ACCESSORIESTP
ACC-00-12800-00	Tubew/Titanium Female Pyramid, 30mmx400mm Aluminum	0888349ACCESSORIESTP
ACC-00-13200-00	Pyramid, 4 Hole Female	0888349ACCESSORIESTP
ACC-00-13700-00	BASE, 4-HOLE, ROTATING PYRAMID(136kg-TITANE)	0888349ACCESSORIESTP
ACC-00-13800-00	Base, 3 Prong, Rotating Pyramid	0888349ACCESSORIESTP
ACC-00-14000-00	Pyramid, Rotating, Female	0888349ACCESSORIESTP
ACC-00-14900-00	TUBE, 12" GRAPHITE 4MM WALL	0888349ACCESSORIESTP
ACC-00-20100-00	ALIGNEMENT JIG PYRAMID, LARGE PYRAMID W/10 MM BOLT	0888349ACCESSORIESTP
ACC-00-20201-00	34mm Titanium Tube Clamp, Rated to 500 lb	0888349ACCESSORIESTP
ACC-00-20202-00	Ear Connector for 34mm Sys	0888349ACCESSORIESTP
ACC-00-20203-00	Carbon Pylon Tube 34MM	0888349ACCESSORIESTP