# 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: September 22nd, 2023** |
|---|---|

| **Legal Manufacturer** | **EU Authorized Representative (EC REP)** |
|---|---|
| **PROTEOR USA, LLC**<br>3 Morgan<br>Irvine, CA 92618<br>USA | **PROTEOR SAS**<br>6 rue de la Redoute<br>21850 Saint-Apollinaire<br>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**<br>143/147, Boulevard Anatole France<br>93285 SAINT-DENIS CEDEX<br>FRANCE |

| **This certificate is issued by:** | **Authorized Signature:** |
|---|---|
| **PROTEOR SAS**<br>**6 rue de la Redoute**<br>**21850 Saint APOLLINAIRE**<br>**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<br>3 Morgan, Irvine, CA 92618<br>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<br>6 rue de la Redoute, 21850 Saint-Apollinaire<br>FRANCE |
| **MDR Assessment Route:** | Self-certification by Medical Device Regulation Article 52, Section 7<br>Article 19: EU Declaration of Conformity<br>Article 15: Person responsible for regulatory compliance |

September 22nd, 2023

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 | Agilix™ | 0888349AGILIXYV |
| KIT-00-1136U-00 | AGILIX Heel Stiffening Bumper Kit | 0888349AGILIXYV |
| F10 | DynAdapt™ | 0888349DYNADAPTGR |
| KIT-00-1137U-00 | DYNADAPT Heel Stiffening Bumper Kit | 0888349DYNADAPTGR |
| FS3 | Highlander® | 0888349HIGHLANDER7R |
| FS3-H5 | Highlander® Max | 0888349HIGHLANDERMAXSJ |
| KIT-00-1130U-00 | HIGHLANDER Heel Stiffening Bumper Kit | 0888349HIGHLANDER7R |
| FS1 | Sierra® | 0888349SIERRA8F |
| KIT-00-1135U-00 | SIERRA Heel Stiffening Bumper Kit | 0888349SIERRA8F |
| FS2 | Pacifica® | 0888349PACIFICA8P |
| KIT-00-1134U-00 | PACIFICA Heel Stiffening Bumper Kit | 0888349PACIFICA8P |
| FS4 | Pacifica® LP | 0888349PACIFICALP5D |
| KIT-00-1132U-00 | PACIFICA LP Heel Stiffening Bumper Kit | 0888349PACIFICALP5D |
| F20 | ShockWave™ | 0888349SHOCKWAVE3Q |
| KIT-00-1146U-00 | SHOCKWAVE Heel Stiffening Bumper Kit | 0888349SHOCKWAVE3Q |
| F13 | Exalto® | 0888349EXALTO76 |
| KIT-00-1148U-00 | EXALTO Heel Stiffening Bumper Kit | 0888349EXALTO76 |
| RM3 | Kinterra | 0888349KINTERRA3ZB |
| KIT-00-1147U-00 | KINTERRA Heel Stiffening Bumper Kit | 0888349KINTERRA3ZB |