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 1236 West Southern Ave, Suite 101 Tempe, AZ 85282 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
RUSH Foot and Prosthetic Plate

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 RUSH Foot and Prosthetic Plate

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:	RUSH Foot and Prosthetic Plate
Legal Manufacturer: (Name on Label)	PROTEOR USA, LLC 1236 West Southern Ave, Suite 101, Tempe, AZ 85282
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 SRN: FR-AR-000008332
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
ROG-XX-X-XX	RUSH ROGUE Foot	08402056RUSHROGUEQ3
EVQR-XX-X-XX	RUSH ROGUE EVAQ8 Foot	08402056RUSHROGUEQ3
H2R-XX-X-XX	RUSH ROGUE H2O Foot	08402056RUSHROGUEQ3
ROG2-XX-X-XX	RUSH ROGUE 2 Foot	08402056RUSHROGUE2EL
EVQR2-XX-X-XX	RUSH ROGUE 2 EVAQ8 Foot	08402056RUSHROGUE2EL
H2R2-XX-X-XX	RUSH ROGUE 2 H2O Foot	08402056RUSHROGUE2EL
HIP-XX-X-XX	RUSH HiPro	08402056RUSHHiProX7
EVQH-XX-X-XX	RUSH HiPro EVAQ8 Foot	08402056RUSHHiProX7
H2H-XX-X-XX	RUSH HiPro H2O Foot	08402056RUSHHiProX7
RAM-XX-X-XX	RUSH RAMPAGE	08402056RUSHRampage8J
EVRAM-XX-X-XX	RUSH RAMPAGE EVAQ8 Foot	08402056RUSHRampage8J
H2RAM-XX-X-XX	RUSH RAMPAGE H2O Foot	08402056RUSHRampage8J
RAMLP-XX-X-XX	RUSH RAMPAGE LP	08402056RUSHRampageLP7B
EVRAMLP-XX-X-XX	RUSH RAMPAGE LP EVAQ8 Foot	08402056RUSHRampageLP7B
H2RAMLP-XX-X-XX	RUSH RAMPAGE LP H2O Foot	08402056RUSHRampageLP7B
EVRB	RUSH EVAQ8 Rebuild Kit	08402056RUSHEVAQ8K3
EVRV	RUSH EVAQ8 Release Valve	08402056RUSHEVAQ8K3
CHO-XX-X-XX	RUSH Chopart Foot	08402056RUSHChopartPlat8G
ROV-XX-X-XX	RUSH ROVER Foot	08402056RUSHROVERRQ
KID-XX-X-XX	RUSH Kid Foot	08402056RUSHKidVE
FS-XX-XX	Foot Shell	08402056RUSHACCESS3H
SS	Spectra™ Sock	08402056RUSHACCESS3H

Version History

Version	Compiled by	Date	Description
1.0	Valery BARBOUR	01/11/2021	Change of EU Rep to PROTEOR SAS
2.0	Valery BARBOUR	05/25/2021	Compliance to EU MDR 2017/745
3.0	Valery BARBOUR	06/29/2021	Addition of Rush ROGUE2 Range
4.0	Valery BARBOUR	03/23/2022	Modification of Part/Catalogue Number
5.0	Valery BARBOUR	03/24/2022	Addition of manufacturer SRN