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: April 21st, 2022**

Legal Manufacturer	**EU Authorized Representative (EC REP)**
Nabtesco Corporation **Accessibility Innovations Company** 35 Uozakihamamachi Higashinada-ku Kobe, 658-0024 Japan	**PROTEOR SAS** 6 rue de la Redoute 21850 Saint APOLLINAIRE France
SRN: JP-MF-000015901	**SRN:** FR-AR-000008332

Product Details, Names or Trade Names
Hybrid knee NI-C311/NI-C311s/NI-C313/NI-C313s

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 Nabtesco Corporation Accessibility Innovations Company and is provided pursuant of the European Authorized Representative agreement (Mandate) between PROTEOR SAS and Nabtesco Corporation Accessibility Innovations Company. 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 Nabtesco Corporation Accessibility Innovations Company 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.

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EU DECLARATION OF CONFORMITY

Manufacturer name and address:	**Nabtesco Corporation** **Accessibility Innovations Company** 35 Uozakihamamachi Higashinada-ku Kobe, 658-0024 Japan Phone: +81 78-413-2724 Fax: +81 78-413-2725 E-mail: Welfare@nabtesco.com
SRN (Single Registration Number):	JP-MF-000015901
Authorized Representative name and address:	**PROTEOR SAS** 6 rue de la Redoute 21850 Saint APOLLINAIRE France
SRN (Single Registration Number):	FR-AR-000008332

We, Nabtesco Corporation hereby declare under our sole responsibility that the device(s) listed in the attached Annex comply(ies) with the provisions of the REGULATION (EU) 2017/745.

The device(s) is/are Class Ⅰ following Rule 1 and 13 of Annex VIII of REGULATION (EU) 2017/745.

The Conformity Assessment Procedure has been performed following Art.19 and Art. 52 (7), and Technical Documentation was drawn up following Annex II and III of the Regulation (EU) 2017/745.

The following Standards have been used and in relation to which conformity is declared:

- ISO10328:2016 Prosthetics -Structural testing of lower-limb prostheses-Requirements and test methods.

- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

The following regulations/directives have been used and in relation to which conformity is declared:

- Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

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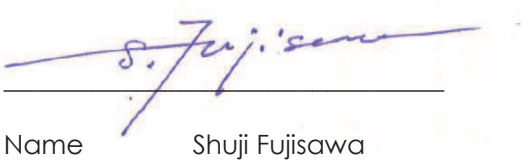
-REACH Regulation: concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

- RoHS Directive: DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

-WEEE Directive: DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE)

The present declaration is in conformity with Regulation (EU) 2017/745 .



Name Shuji Fujisawa
Position General Manager of Assistive Products Department
Accessibility Innovations Company,
Nabtesco Corporation
Place & Date Kobe, Japan on April 21, 2022

Annex - List of Devices Covered by the Declaration of Conformity

Commercial name/ Trade name	Hybrid knee
Model	NI-C311/NI-C311s/NI-C313/NI-C313s
Description	Prosthetic knee joint
Intended Purpose	This device, Hybrid knee, is designed and manufactured to be used as a prosthetic knee joint for patients who amputated / lost upper than knee joint level.
Class	1
Classification rule applied	Rule 1,13
BASIC UDI - DI	4562204180729
CND code	Y0624

Version History

Version	Compiled by	Date	Description
1.0	Shuji Fujisawa	April 21st 2022	Change of EU Rep to PROTEOR SAS