

## Declaration of Conformity Certificate

Manufacturer:	BL Tech Co., Ltd.
Address:	84 Toegyeonngong-ro
Address:	Chuncheon-si. Gangwon-do
Country:	Republic of Korea
Phone Number:	+82 33 264 2686
Single Registration Number:	KR-MF-000013035

We  
 Declare with sole responsibility, that our product/s:

CND/ EMDN Code	CND/ EMDN Description	Product Code	Product Name	Classification Rationale per MDR
M03050202	BANDAGES AND SPLINTS - OTHERS	NEAL CAST	Casting Tape	Class I (According to Rule 1 of Chapter III clause 4 for NON-INVASIVE DEVICES in MDR Annex VIII)

meet, the general safety and performance requirements of Regulation (EU) 2017/745 pertaining to medical devices.  
 Pathway of conformity per Article 19 and Annex IV.

Basic UDI-DI: **8809270466606**

The product(s) identified above meet requirements of the Medical Devices Regulation by meeting the following standards

Standard No.	Standard Description
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ASTM F1536-95(2015)	Standard Test Method for Determining Strength and Setting Time of Synthetic Water-Activated Polyurethane Fiberglass Orthopaedic Casting Tape

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 11 of Regulation (EU) 2017/745.

May 20, 2021

Date of Issue

JIN-WOO BAE

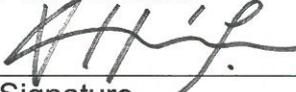
Printed Name

President

Title

Chuncheon-si. Gangwon-do, South  
 Korea

Place of Issue

  
 Signature

BL Tech Co., Ltd.

Company

