

## EU DECLARATION OF CONFORMITY

### REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

This declaration of conformity is issued under the sole responsibility of NEW CAST INDUSTRY CO. LTD., in compliance to Article 19 of EU MDR 2017/745.

We hereby declare that the medical device specified above meet the provision of the Annex IV of Regulation EU MDR 2017/745 for medical devices.

<b>Manufacturer Name:</b>	<b>NEW CAST INDUSTRY CO. LTD.,</b>
<b>Manufacturer Address:</b>	11, Cheoyongsaneop 5-gil, Cheongnyang-myeon, Ulsu-gun, Ulsan, Korea
<b>Manufacturer Registration Number:</b>	107-86-01376
<b>SRN:</b>	KR-MF-000025288
<b>Authorized Representative Name :</b>	<b>SANUSMED DISTRIBUTION LTD.,</b>
<b>Authorized Representative Address:</b>	Doamna Oltea str., no 33, 1st floor, Office no 10, Bucharest, 2nd District, 020231 Romania,
<b>SRN:</b>	RO-AR-000001006
<b>Product Name:</b>	HM SPLINT
<b>Catalogue/Reference No.:</b>	HMS330, HMS388, HMS438, HMS476, HMS576, HMS5114, HMS3450, HMS4450, HMS5450
<b>Intended to Use:</b>	Orthopedic Splint The HM Splint products are indicated for rigid external immobilization. The purposes for external rigid immobilization include immobilization of bone fractures, treatment of soft tissue and joint injuries, immobilization within treatments for correction or prevention of anatomical deformities.
<b>Basic UDI-DI:</b>	880936708HMSplintGB

<b>Product Classification / Classification Rule:</b>	Class I by Rule 1 of Annex VIII, MDR 2017/745
<b>GMDN Code:</b>	8809367080005,8809367080012,8809367080029,8809367080036, 8809367080043, 8809367080050,8809367080586, 8809367080593, 8809367080609
<b>EMDN Code:</b>	M0199 - Wool and Synthetic Cotton M030599 - Immobilization Systems and Devices Other
<b>Conformity Assessment Route:</b>  (Mention the conformity route as per MDR article 52)	Annex-IV (Annex II & III)
	Annex-IX (Chapter I & III)
	Annex-IX (Chapter II)
	Annex-X
	Annex-XI (Section A)
	Annex-XI (Section B)
<b>Harmonized standards / Common Specifications:</b>	The products listed on this Declaration of Conformity are in accordance with the quality management system according to EN ISO 13485- Requirements for regulatory purposes, and fulfils the general safety and performance requirements of the regulation (EU) 2017/745.

It's here declared that the device, to which this declaration is addressed to, is commercialized in non-sterile package.

It's here declared that the subscribing company will keep all the documents mentioned in Annex I, II and III of Regulation (EU) 2017/745 available for Competent Authority for a period of 10 years from the last production of the device to which this declaration is addressed to.

The CE marking has been affixed on the product according to Annex V of the Regulation (EU) 2017/745.

Signed for and on behalf of:

**NEW CAST INDUSTRY CO. LTD.,**

11, Cheoyongsaneop 5-gil, Cheongnyang-myeon, Ulju-gun, Ulsan, Korea

Place of issue: Ulsan, Korea

Date of issue: 19.07.2022

Name: Mr. Kim Jong Gwan

Title: President **New Cast Industry Co.Ltd.**

Signature:

  
