

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.

Manufacturer Name:	NEW CAST INDUSTRY CO. LTD.,
Manufacturer Address:	11, Cheoyongsaneop 5-gil, Cheongnyang-myeon, Ulju-gun, Ulsan, Korea
Manufacturer Registration Number:	107-86-01376
SRN:	KR-MF-000025288
Authorised Representative Name :	SANUSMED DISTRIBUTION LTD.,
Authorised Representative Address:	Doamna Oltea street no.33, 1st floor, Office no.10, Bucharest, 2nd District, 020231 Romania
SRN:	RO-AR-000001006
Product Name:	HM CAST
Catalogue/Reference No.:	HMC225, HMC225(T), HMC245, HMC335, HMC335(T), HMC350, HMC370, HMC435, HMC435(T), HMC455, HMC490, HMC555, HMC590
Intended to Use:	Orthopedic Cast The HM Cast 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.
Basic UDI-DI:	880936708HMCastZL
Product Classification / Classification Rule:	Class I by Rule 1 of Annex VIII, MDR 2017/745

GMDN Code:	8809367080104, 8809367080128, 8809367080142, 8809367080166, 8809367080203, 8809367080210, 8809367080227, 8809367080241, 8809367080258, 8809367080265
EMDN Code:	- M0199 - Wool and Synthetic Cotton - M03030201 - Tubular Mesh - M030599 - Immobilization Systems and Devices – Other
Conformity Assessment Route: (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)
Harmonized standards / Common Specifications:	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

Signature:

New Cast Industry Co.Ltd!


PRESIDENT/J.G.KIM

