



**Declaration of Conformity**  
**HM CAST**

No# 5949096177.02  
Page 1 of 2

We,

**S.C. SANUSMED DISTRIBUTION S.R.L.**  
**Doamna Oltea str., no 33, 1st floor, Office no 10,**  
**Bucharest, 2nd District,**  
**020231 Romania,**  
**(SRN: RO-AR-000001006)**

acting as European Authorized Representative, hereby declare under our own responsibility, that this product family complies with the applicable regulations of the regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (MDR).

Product name: **HM CAST**  
Basic UDI-DI: **5949096177HMCAST01HL**

Intended purpose: **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.**

Conformity assessment route: **Annex II+III**  
Classification rule: **1**  
Classification: **I**

The Declaration of Conformity is performed in accordance with the quality management system according to EN ISO 13485 and fulfills the general safety and performance requirements of the regulation (EU) 2017/745.

**Manufacturer:**  
**New Cast Industry Co., Ltd,**  
**11, Cheoyongsaneop 5-gil, Cheongnyang-myeon, Ulju-gun, Ulsan, Korea**  
(SRN: Not issued yet)

**European Authorized Representative:**  
**S.C. SANUSMED DISTRIBUTION S.R.L.**  
**Doamna Oltea str., no 33, 1st floor, Office no 10, Bucharest, 2nd District, 020231 Romania,**  
**(SRN: RO-AR-000001006)**

Date of issue: 14.05.2021

**Lucian Temelcea**  
Director

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Completed and released:  
Sanusmed Distribution SRL.  
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Page 2 of 2

<b>Article</b>	<b>Description</b>	<b>Reference</b>
01-HMC225	HM CAST 2 inch (5,08 cm x 25 cm)	HMC225
02-HMC245	HM CAST 2 inch (5,08 cm x 45 cm)	HMC245
03-HMC335	HM CAST 3 inch (7,62 cm x 35 cm)	HMC335
04-HMC350	HM CAST 3 inch (7,62 cm x 50 cm)	HMC350
05-HMC370	HM CAST 3 inch (7,62 cm x 70 cm)	HMC370
06-HMC435	HM CAST 4 inch (10,16 cm x 35 cm)	HMC435
07-HMC455	HM CAST 4 inch (10,16 cm x 55 cm)	HMC455
08-HMC490	HM CAST 4 inch (10,16 cm x 90 cm)	HMC490
09-HMC555	HM CAST 5 inch (12,7 cm x 55 cm)	HMC555
10-HMC590	HM CAST 5 inch (12,7 cm x 90 cm)	HMC590