



**Declaration of Conformity  
HM CASTING TAPE**

No# 5949096177.04  
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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 CASTING TAPE**  
Basic UDI-DI: **5949096177HMCASTTAPE0366**

Intended purpose: **The HM CASTING TAPE products are is 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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<b>Article</b>	<b>Description</b>	<b>Reference</b>
01-HMC2	HM CASTING TAPE 2 inch (5 cm x 360 cm)	HMC2
02-HMC3	HM CASTING TAPE 3 inch (7,6 cm x 360 cm)	HMC3
03-HMC4	HM CASTING TAPE 4 inch (10 cm x 360 cm)	HMC4
04-HMC5	HM CASTING TAPE 5 inch (12,7 cm x 360 cm)	HMC5