



**Declaration of Conformity  
HM SPLINT**

No# 5949096177.03  
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 SPLINT**  
Basic UDI-DI: **5949096177HMSPLINT02FB**

Intended purpose: **The HM Splint 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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**Declaration of Conformity  
HM CAST**

No# 5949096177.02  
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<b>Article</b>	<b>Description</b>	<b>Reference</b>
01-HMS330	HM SPLINT 3 inch (7,62 cm x 30 cm)	HMS330
02-HMS388	HM SPLINT 3 inch (7,62 cm x 88 cm)	HMS388
03-HMS438	HM SPLINT 4 inch (10,16 cm x 38 cm)	HMS438
04-HMS476	HM SPLINT 4 inch (10,16 cm x 76 cm)	HMS476
05-HMS576	HM SPLINT 5 inch (12,7 cm x 76 cm)	HMS576
06-HMS5114	HM SPLINT 5 inch (12,7 cm x 114 cm)	HMS5114
07-HMS3450	HM SPLINT 3 inch (7,62 cm x 450 cm)	HMS3450
08-HMS4450	HM SPLINT 4 inch (10,16 cm x 450 cm)	HMS4450
09-HMS5450	HM SPLINT 5 inch (12,7 cm x 450 cm)	HMS5450