



Declaration of Conformity (EU)

Ovation Medical hereby declares under its sole responsibility that the medical device/ device family **Versa-Fit** and **Nu-Form Versa-Fit Thumb Spica Devices** meets all the provisions of the

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL,
which apply.

Manufacturer: Ovation Medical (5155 Clarenton Drive 200, Agoura Hill, California 91301, United States) hereby declares under its sole responsibility that the medical device/ device family Thumb Spica Devices (Classification I) meets all the provisions of the above regulation.

Product Group: Versa-Fit Thumb Spica, Nu-Form Versa-Fit Thumb Spica

Product Classification: Class I (Annex VIII, Rule 1)

CND Group: Y0606 (ORTHOSIS, UPPER EXTREMITY)

Basic UDI-DI: 081004743E22




Authorized Representative: MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany

We hereby declare the conformity of above-mentioned medical device/ device family according to the European Regulation 2017/745.

The above-mentioned medical device/ device family was initially CE released in the year 2017/2020 respectively.

The list of the medical devices covered by this Declaration of Conformity is attached.

Place and Date : Agoura Hills, 28 May 2021

Date	Name	Function	Document Version	Signature
5/28/2021	Henry Alvarado	Project Leader	A	
5/28/2021	Cathy McCann	Regulatory Affair/ Risk Management		
5/28/2021	Kenji Watabe	Quality Control		



Articles in scope

Article number	Product	Basic UDI-DI	(GS1) GTIN
50072-2	Versa-Fit Thumb Spica Left, X-Small	081004743E22	00810047432432
50072-5	Nu-Form Versa-Fit Thumb Spica Left, X-Small	081004743E22	00810047432449
50075-2	Versa-Fit Thumb Spica Left, Standard Size	081004743E22	00810047432456
50075-5	Nu-Form Versa-Fit Thumb Spica Left, Standard Size	081004743E22	00810047432470
50078-2	Versa-Fit Thumb Spica Left, X-Large	081004743E22	00810047432487
50078-5	Nu-Form Versa-Fit Thumb Spica Left, X-Large	081004743E22	00810047432500
51072-2	Versa-Fit Thumb Spica Right, X-Small	081004743E22	00810047432517
51072-5	Nu-Form Versa-Fit Thumb Spica Right, X-Small	081004743E22	00810047432524
51075-2	Versa-Fit Thumb Spica Right, Standard Size	081004743E22	00810047432531
51075-5	Nu-Form Versa-Fit Thumb Spica Right, Standard Size	081004743E22	00810047432555
51078-2	Versa-Fit Thumb Spica Right, X-Large	081004743E22	00810047432562
51078-5	Nu-Form Versa-Fit Thumb Spica Right, X-Large	081004743E22	00810047432586