



Déclaration de conformité UE EU Declaration of conformity

Cette déclaration de conformité est établie sous la seule responsabilité du fabricant légal :

This declaration of conformity is issued under the sole responsibility of the legal manufacturer:

THUASNE
120 rue Marius AUFAN
92300 Levallois-Perret
France

Cette déclaration certifie que - *This is to certify that:*

LIGAFLEX IMMO

Code style	Désignation / Description	Basic-UDI-DI
240003	LIGAFLEX IMMO	311179FR022ABG8
240004	LIGAFLEX IMMO	311179FR022ABG8
241003	LIGAFLEX IMMO 0°	311179FR022AAG6
241004	LIGAFLEX IMMO 0°	311179FR022AAG6
242003	LIGAFLEX IMMO 20°	311179FR022AAG6
242004	LIGAFLEX IMMO 20°	311179FR022AAG6

Attelles de genoux / *Knee splints*

Modèle/Model: Ligaflex Immo 3 volets/ *3 panels*

Référence - Reference	Désignation - Designation	UDI-DI
24000320100499	Ligaflex Immo Size 1	3111790238829
24000320200499	Ligaflex Immo Size 2	3111790238836
24000320300499	Ligaflex Immo Size 3	3111790238843
24000320400499	Ligaflex Immo Size 4	3111790238850
24000420100499	Ligaflex Immo Size 1	3111790047339
24000420200499	Ligaflex Immo Size 2	3111790047346
24000420300499	Ligaflex Immo Size 3	3111790047353
24000420400499	Ligaflex Immo Size 4	3111790047360


Modèle/Model: Ligaflex Immo 0°

Référence - Reference	Désignation - Designation	UDI-DI
24100320005004	Ligaflex Immo 0° Height 50cm Size S	3111790238942
24100320105004	Ligaflex Immo 0° Height 50cm Size M	3111790238959
24100320106004	Ligaflex Immo 0° Height 60cm Size M	3111790238966
24100320205004	Ligaflex Immo 0° Height 50cm Size L	3111790238973
24100320206004	Ligaflex Immo 0° Height 60cm Size L	3111790238980
24100320305004	Ligaflex Immo 0° Height 50cm Size XL	3111790238997
24100320306004	Ligaflex Immo 0° Height 60cm Size XL	3111790239000
24100450104004	Ligaflex Immo 0° Height 40cm Size S	3111790047377
24100450105004	Ligaflex Immo 0° Height 50cm Size S	3111790047384
24100450205004	Ligaflex Immo 0° Height 50cm Size M	3111790047391
24100450206004	Ligaflex Immo 0° Height 60cm Size M	3111790047407
24100450305004	Ligaflex Immo 0° Height 50cm Size L	3111790047414
24100450306004	Ligaflex Immo 0° Height 60cm Size L	3111790047421
24100450405004	Ligaflex Immo 0° Height 50cm Size XL	3111790047438
24100450406004	Ligaflex Immo 0° Height 60cm Size XL	3111790047445

Modèle/Model: Ligaflex Immo 20°

Référence - Reference	Désignation - Designation	UDI-DI
24200320005004	Ligaflex Immo 20° Height 50cm Size S	3111790239086
24200320105004	Ligaflex Immo 20° Height 50cm Size M	3111790239093
24200320106004	Ligaflex Immo 20° Height 60cm Size M	3111790239109
24200320205004	Ligaflex Immo 20° Height 50cm Size L	3111790239116
24200320206004	Ligaflex Immo 20° Height 60cm Size L	3111790239123
24200320305004	Ligaflex Immo 20° Height 50cm Size XL	3111790239130
24200320306004	Ligaflex Immo 20° Height 60cm Size XL	3111790239147
24200450105004	Ligaflex Immo 20° Height 50cm Size S	3111790047452
24200450205004	Ligaflex Immo 20° Height 50cm Size M	3111790047469
24200450206004	Ligaflex Immo 20° Height 60cm Size M	3111790047476
24200450305004	Ligaflex Immo 20° Height 50cm Size L	3111790047483
24200450306004	Ligaflex Immo 20° Height 60cm Size L	3111790047490
24200450405004	Ligaflex Immo 20° Height 50cm Size XL	3111790047506
24200450406004	Ligaflex Immo 20° Height 60cm Size XL	3111790047513

Nomenclature	Code	Description
GMDN	Y061209	Orthèses de genou / Orthosis, Knee



CND	41065	Orthèses de genou / Knee orthosis
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Sont des dispositifs médicaux de classe I tels que définis à l'annexe VIII du règlement (UE) 2017/745.

Sont conformes aux exigences de l'annexe I du règlement (UE) 2017/745 concernant les dispositifs médicaux de classe I.

Are class I medical devices as defined in the Annex VIII of the Regulation (EU) 2017/745.

Are in conformity with the requirements of Regulation (EU) 2017/745 Annex I relating to Class I medical devices.

Date de marquage CE - CE marking date :

- Ligaflex Immo 3 volets/ 3 panels : Juillet/July 1997.
- Ligaflex Immo 0°/20° : 2009

Pour Thuasne - For Thuasne:

François Marchal,
Directeur Affaires Réglementaires - Regulatory Affairs Director

Lieu - Place: 27 rue de la Jomayère, 42100 Saint Etienne - France

Date: 13 juillet 2021 | 01:05:19 CEST

Signature:

DocuSigned by:

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