



EC Declaration of Conformity

Manufacturers Name: Anatomy Supply Partners, LLC

Manufacturers Address: 7800 Third Flag Parkway, Austell, GA 30168 USA

SRN (Single Registration Number): US-MF-000013500

Authorized Representative Name: CEpartner4U

Authorized Representative Address: Esdoornlaan 13, 3951 DB Maarn, The Netherlands

Basic UDI-DI: 08402161700001CY

Name of the Device (s): Rolyan Premium Heel/Elbow Protectors, Small
Rolyan Premium Heel/Elbow Protectors, Medium
Rolyan Premium Heel/Elbow Protectors, Large
Rolyan Premium Heel/Elbow Protectors, X-Large
Rolyan Premium Heel/Elbow Protectors, XX-Large
Rolyan Premium Gel Heel/Elbow Protector, Small
Rolyan Premium Gel Heel/Elbow Protector, Medium
Rolyan Premium Gel Heel/Elbow Protector, Large
Rolyan Premium Gel Heel/Elbow Protector, X-Large
Rolyan Premium Gel Heel/Elbow Protector, XX-Large
Rolyan Elbow/Heel Protectors, Yellow, S, Gel Protector
Rolyan Elbow/Heel Protectors, Blue, M/L, Gel Protector
Rolyan Elbow/Heel Protectors, Green, XL, Gel Protector
Rolyan Elbow/Heel Protectors, Blue, M/L, Foam Protector
Rolyan Elbow/Heel Protectors, Yellow, S, Foam Protector
Rolyan Elbow/Heel Protectors, Green, XL, Foam Protector

Intended Purpose:

Product code: Cushion for protecting heel/elbow.
GMDN 32858 Elbow/Ankle Protector

Risk Classification: I, Rule 1 Noninvasive Devices

Declaration Type: CE Mark Self-Declaration

Conformity assessment route: Anatomy Supply Partners, LLC uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:

Class I: EC conformity declaration according to Annex II + Annex III.

This self-declaration of conformity is issued under the sole responsibility of Anatomy Supply Partners, LLC. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System compliance to ISO 13485.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Sabrina Moore

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Sabrina Moore
Director of Quality & Regulatory
Compliance

Place and date (dd.mm.yyyy) of issue:

13.06.2022

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Elbow/Ankle Protector

Catalog number	Description
700001	Rolyan Premium Heel/Elbow Protectors, Small
700002	Rolyan Premium Heel/Elbow Protectors, Medium
700003	Rolyan Premium Heel/Elbow Protectors, Large
700004	Rolyan Premium Heel/Elbow Protectors, X-Large
700005	Rolyan Premium Heel/Elbow Protectors, XX-Large
700101	Rolyan Premium Gel Heel/Elbow Protector, Small
700102	Rolyan Premium Gel Heel/Elbow Protector, Medium
700103	Rolyan Premium Gel Heel/Elbow Protector, Large
700104	Rolyan Premium Gel Heel/Elbow Protector, X-Large
700105	Rolyan Premium Gel Heel/Elbow Protector, XX-Large
A730001	Rolyan Elbow/Heel Protectors, Yellow, S, Gel Protector
A730002	Rolyan Elbow/Heel Protectors, Blue, M/L, Gel Protector
A730003	Rolyan Elbow/Heel Protectors, Green, XL, Gel Protector
A731M	Rolyan Elbow/Heel Protectors, Blue, M/L, Foam Protector
A731S	Rolyan Elbow/Heel Protectors, Yellow, S, Foam Protector
A731XL	Rolyan Elbow/Heel Protectors, Green, XL, Foam Protector

Harmonized Standards

Reference number	Description
BS EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
BS EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
BS EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
IEC 62366-1:2015	Corrigendum 1 - Medical Devices - Part 1: Application of Usability Engineering to Medical Devices