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EU Declaration of Conformity

Manufacturer…….: Elbnova GmbH
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Tel: +49 40 28789833
Website: www.elbnova.com
Email: info@elbnova.com
SRN: DE-MF-000050365

Product……..: Product Name: Gel Positioning Pad
Model Name: Refer to Appendix
Basic UDI-DI: 426254289GelPadWH
Classification: Class I, Rule 1 in Annex VIII, Regulation (EU) 2017/745
Intended Purpose: To provide pressure relief and constant support

This declaration of conformity is issued under the sole responsibility of Elbnova GmbH. We hereby declare that the medical device specified above meets the provisions of the EU Medical Device Regulation (MDR) 2017/745. This device is in conformity to the MDR 2017/745 that provides for the issuing of the EU Declaration of Conformity (DOC). All supporting documentation is retained at the premises of the manufacturer.

Signature:

Ehsan Ebrahim Kani

CEO

Date and place of issue:

Hamburg, Germany

2025-11-13

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Appendix – Model Name and UDI-DI:

Item	Model Name	Code	UDI-DI
1	Closed Gel Positioning Head Ring (Adult)	EG-100	4262542890082
2	Closed Gel Positioning Head Ring (Children)	EG-110	4262542890075
3	Open Gel Positioning Head Ring (Adult)	EG-130	4262542890068
4	Open Gel Positioning Head Ring (Children)	EG-140	4262542890051
5	Gel Positioning Pad – Prone – Head	EG-160	4262542890044
6	Gel Positioning Body Pad	EG-200	4262542890204
7	Textured Gel Positioning Body Pad	EG-220	4262542890037
8	Gel Positioning Chair Pad	EG-300	4262542890020
9	Textured Gel Positioning Chair Pad	EG-310	4262542890013
10	Gel Positioning Lateral Pad	EG-400	4262542890105
11	Gel Positioning Shoulder Pad	EG-500	4262542890167
12	Gel Positioning Heel Pad	EG-600	4262542890143
13	Gel Positioning Armboard Pad	EG-700	4262542890112
14	Gel Positioning Lateral Armboard Pad	EG-710	4262542890198

Signature:

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CEO

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