Manufacturer's EU Declaration of Conformity

CE marking in accordance with the REGULATION (EU) 2017/745 on Medical Devices (MDR)

This EU Declaration of Conformity is issued under the sole responsibility of Culsana B.V. We hereby declare that each medical device covered by this Declaration conforms to the applicable requirements of REGULATION (EU) 2017/745 on medical devices (MDR).

Manufacturers Name:	Culsana B.V.
Manufacturers Adress:	Laarakkerweg 9, 5061 JR, Oisterwijk The Netherlands
Manufacturers SRN: (Single Registration Number)	NL-MF-000002052



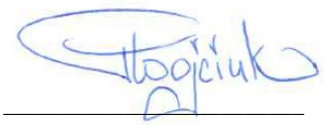
Brand Name:	Culsana
Medical Device:	Seat Cushions
Model Number:	4050
Basic UDI:	8720299509313405ONN
Intended purpose:	Intended to provide pressure redistribution, support and comfort during prolonged sitting, helping to prevent pressure-related skin problems.
Classification:	Class I according to Rule 1, Annex VIII of REGULATION (EU) 2017/745 on Medical Devices

No Common Specifications (CS) have been applied.

Additional information:

Standards applied:	NEN-EN-ISO 14971:2019 NEN-ISO 16840-2:2018
The Product has been tested and evaluated in accordance with the following standards:	EN 597-1: 2015 EN 597-2:2015 EN 1021-1:2014 EN 1021-2:2014
The product has been designed and manufactured under a certified quality management system in accordance with:	UNI-CEI-ISO 13485:2021

Signed for and on behalf of Culsana B.V.:

Signature:	Date:	Place:
	*19-11-2026*	Oisterwijk, Netherlands
Patrycja Wojciuk, Manager Quality & Regulatory	*dd-mm-yyyy*	City, land

Document Number: DOC4050-2026-01