

CE DECLARATION OF CONFORMITY REBACARE® CUSHION LINE + COVERS



DYNAMIC POSITIONING ORTHESIS (DPO)

CE FARMATEC: NL-CA002-2014-33425

SRN: 8720256429

BASIC UDI-DI: 87202564297775F

Complies with:

Dynamic Positioning Orthosis (DPO) CE Farmatec: NL-CA002-2014-33425 classified as Class I according to Annex VIII rule 1 and is in conformity with the general safety and performance requirements and provisions of the Regulation MDR 2017/745 and (are)(is) in conformity with the relevant harmonised standards: ISO 14971:2019, ISO 15223-1:2016 (corr. 2017-04) and is subject to the procedure set out in Annex II & III of the Regulation MDR 2017/745.

Company Name: REBACARE® BV
Address: Sasker van Heringawei 12
Postal Code: 9034 GD
Place: Marsum
Country: The Netherlands

Name: R. de Vries
Function: CEO
Place: Marsum
Date: September 2021

Name: T.D. Hansma
Function: Manager QA & QC
Place: Marsum
Date: September 2021

Signature R. de Vries

Signature T.D. Hansma