Beiersdorf

## Beiersdorf international documentation system BEC.10297621.000.02 DoC Adjustable Ankle Brace

Released: 17.10.23-...

Page 1 of 2

Printed: 17.10.2023 14:18:14

## **EU – Declaration of Conformity**

We, the company,

Beiersdorf AG SRN DE-MF-000014151

## 20245 Hamburg Germany

hereby declare in our sole responsibility as legal manufacturer that the device(s)

02579-00000-47	HP SP ANBR NEO ALL 1 DE_FR_IT
02579-00001-47	HP SP ANBR NEO ALL 1 DE_FR_NL
02579-00006-47	EPL SP ANBR NEO ALL 1 EN
02579-00007-47	EPL SP ANBR NEO ALL 1 EN
02579-00007-48	EPL SP ANBR NEO ALL 1 EN
02579-00011-47	HP SP ANBR NEO ALL 1 INT
02579-00013-48	HP SP ANBR NEO ALL 1 EN_MS

Product Identification:

Hansaplast® / Elastoplast® Protective Ankle Support

Basic-UDI-DI:

4005800000000000000019D4

Intended Use:

Joint brace to help to provide strength, protection, compression, and

support to stiff, weak, painful, or injured joints

is/are in compliance with Regulation (EU) 2017/745 concerning medical devices.

#### Classification

according to Annex VIII of the Regulation (EU) named above.

class I

## Beiersdorf

# Beiersdorf international documentation system BEC.10297621.000.02 DoC Adjustable Ankle Brace

Released: 17.10.23-...

Page 2 of 2

Printed: 17.10.2023 14:18:14

## **Conformity Assessment Procedure**

according to Article 52(7) and Annex IV of the Regulation (EU) named above.

### **Notified Body**

not applicable for medical device class I.

This declaration is also valid for products which may carry additional labels to comply with local market and regulatory requirements (relabeling).

Hamburg (Germany), 17. 10.

(date

Martina Fraenkel

Manager Regulatory Affairs (Signed for and on behalf of Beiersdorf AG)