

BAUERFEIND AG • TRIEBESER STR. 16 • 07937 ZEULENRODA-TRIEBES • GERMANY

EU Declaration of Conformity

(according to Annex IX of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices)

We,
 Bauerfeind AG
 Triebeser Str. 16
 D-07937 Zeulenroda-Triebes
 SRN: ./.

declare under our sole responsibility that our products:

| Product name | Intended purpose | Basic UDI-DI |
|---------------------------------|--|-----------------------------|
| Sports Ankle Support | Support for stabilizing the ankle using a strap. Designed for athletic activities/exercise. | 4046445ANK0000000J8 |
| Sports Ankle Support Dynamic | Support for stabilizing the ankle. Designed for athletic activities/exercise. | 4046445ANKD0000000VH |
| Sports Knee Support | Support for stabilization of the knee joint and relief of the kneecap using an integrated pad. Designed for athletic activities/exercise. | 4046445KNE00000000PL |
| Sports Compression Knee Support | Circular-knit compression support for stabilizing the knee joint. Designed for athletic activities/exercise. | 4046445SCKS0000000DY |
| Sports Knee Strap | Patellar tendon support for guiding and relieving the patellar tendon on the knee. Designed for athletic activities/exercise. | 4046445SKS000000006S |
| Sports Back Support | Support for stabilizing the back muscles. Designed for athletic activities/exercise. | 4046445BAC00000000ZK |
| Sports Wrist Strap | Support for relief and stabilization of the wrist. Designed for athletic activities/exercise. | 4046445SWS00000000HN |

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CHIEF EXECUTIVE OFFICER

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CHAIRMAN OF THE BOARD

Prof. Hans B. Bauerfeind

BAUERFEIND.COM


| | | |
|------------------------------|--|-----------------------------|
| Sports Elbow Support | Support for protecting the elbow against excessive strain using integrated pads. Designed for athletic activities/exercise. | 4046445ELB0000000DT |
| Sports Elbow Strap | Support for alleviating elbow problems by protecting the forearm muscles. Designed for athletic activities/exercise. | 4046445SES0000000Z9 |
| Sports Elbow Brace | Support for alleviating elbow problems by preventing hyperextension of the joint. Designed for athletic activities/exercise. | 4046445SEB0000000M2 |
| Sports Insoles Ball & Racket | Foot orthoses for increased wearing comfort and for stabilizing the movement of the hindfoot. Designed for athletic activities/exercise. | 4046445SpInbr00000DV |
| Sports Insoles Run & Walk | Foot orthoses for increased wearing comfort and for stabilizing the movement of the hindfoot. Designed for athletic activities/exercise. | 4046445SpInrw00000QE |
| Sports Insoles Ski & Skate | Foot orthoses for increased wearing comfort and for stabilizing the movement of the hindfoot. Designed for athletic activities/exercise. | 4046445SpInss00000PB |


comply with the general safety and performance requirements according to Annex I of Regulation (EU) 2017/745 on medical devices. A notified body is not involved in the conformity assessment procedure.

The products have been classified as risk class I according to Annex VIII, Chapter III of the MDR 2017/745.

They comply with the applicable provisions of Regulation (EU) 2017/745 on medical devices.

Zeulenroda-Triebes, Germany; April 29, 2021


 Ines Exner
 Person responsible – MDR
 Bauerfeind AG


 Petra Schroeder
 Team Leader Regulatory Affairs Int.
 Bauerfeind AG