

EC-Conformity Declaration

(according to Appendix IX of the Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council)

We,
 Bauerfeind AG
 Triebeser Str. 16
 D-07937 Zeulenroda-Triebes
 SRN: DE-MF 000007543

declare in exclusive accountability, that our products

Name	Intended Use	Basis-UDI-DI
Sports Ankle Support	Support for the ankle. The strap gives the ankle stability. Medical product specially designed for sporting activities.	4046445ANK00000000J8
Sports Ankle Support Dynamic	Support for the ankle. Medical product specially designed for sporting activities.	4046445ANKD00000000VH
Sports Knee Support	Support for the knee and gives the knee stability. The integrated pad protects and relieves the kneecap. Medical product specially designed for sporting activities.	4046445KNE00000000PL
Sports Compression Knee Support	It is a circular knit compression support for stabilizing the knee joint. Medical product specially designed for sporting activities.	4046445SCKS00000000DY
Sports Knee Strap	Patellar tendon support to guide and relieve the affected tendon at the knee. Medical product specially designed for sporting activities.	4046445SKS000000006S
Sports Back Support	Support stabilizes the back muscles. Medical product specially designed for sporting activities.	4046445BAC00000000ZK
Sports Wrist Strap	Support to relieve strain and stabilize the wrist. Medical product specially designed for sporting activities.	4046445SWS000000000HN

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Sports Elbow Support	Support prevents excessive strain by interaction with the integrated pads. Medical product specially designed for sporting activities.	4046445ELB0000000DT
Sports Elbow Strap	Support relieves elbow pain. Pad alleviates pain and prevents muscle inflammation. Medical product specially designed for sporting activities.	4046445SES0000000Z9
Sports Elbow Brace	Support relieves elbow pain associated with excessive strain and hyperextension of the elbow joint. Medical product specially designed for sporting activities.	4046445SEB0000000M2
Sports Insoles Ball & Racket	Supportive foot orthosis that makes sports shoes more comfortable to wear and helps stabilize the movement of the hindfoot during athletic activities.	4046445SpInbr00000DV
Sports Insoles Run & Walk	Supportive foot orthosis that makes sports shoes more comfortable to wear and helps stabilize the movement of the hindfoot during athletic activities.	4046445SpInrw00000QE
Sports Insoles Ski & Skate	Supportive foot orthosis that makes sports shoes more comfortable to wear and helps stabilize the movement of the hindfoot during athletic activities.	4046445SpInss00000PB

comply with the General Safety and Performance Requirements according to Annex I of the Medical Device Regulation (EU) 2017/745. Within the conformity evaluation process there has been no participation of a Notified Body.

The products have been classified according to Annex VIII, Chapter III, MDR 2017/745 in risk class I. They correspond to the given provisions of the Regulation (EU) 2017/745 for Medical Devices.

Zeulenroda-Triebes, 26th July 2021

p.o. Ines Exner
 Person Responsible for Regulatory
 Compliance
 Bauerfeind AG



p.o. Petra Schroeder
 Head of Regulatory Affairs Int.
 Bauerfeind AG