

**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
ErgoPad® Sensitive	Orthopedic orthoses are functional orthoses for the feet and are suitable for use in treating and preventing foot complaints.	4046445EPSe000000RN
ErgoPad®soft Diabetes	Orthopedic orthoses are functional orthoses for the feet and are suitable for use in treating and preventing foot complaints.	4046445EPsoDB0000047
ErgoPad® weightflex 2	Orthopedic foot orthosis that is suitable for use in treating and preventing foot conditions. It supports the natural gait pattern thanks to its flexible / medium / stable arch support.	4046445EPwf2000000HP
ErgoPad® redux heel 2	Foot orthosis that is suitable for use in treating and preventing foot conditions.	4046445EPrh2000000FA
ErgoPad® ball & racket	Supportive foot orthoses for increased wearing comfort of sports shoes and for stabilizing the movement of the hindfoot during athletic activities/exercise. Suitable for: Racket and other sports, such as volleyball, handball, basketball, tennis, badminton, squash, golf, football (depending on footwear).	4046445EPbr00000008N

**ADDRESS**

Bauerfeind AG  
 Triebeser Straße 16  
 07937 Zeulenroda-Triebes  
 Germany

**CONTACT**

P +49 (0) 36628 66-1000  
 F +49 (0) 36628 66-1999  
 E info@bauerfeind.com

**DELIVERY ADDRESS**

Weißendorfer Straße 5  
 07937 Zeulenroda-Triebes  
 Germany

Bauerfeind AG  
 AG Jena HRB 206561

**CHIEF EXECUTIVE OFFICER**

Rainer Berthan

**MEMBER OF THE EXECUTIVE BOARD**

Andreas Lauth

**CHAIRMAN OF THE BOARD**

Prof. Hans B. Bauerfeind

**BAUERFEIND.COM**

ErgoPad® run & walk	Supportive foot orthoses for increased wearing comfort of sports shoes and for stabilizing the movement of the hindfoot during athletic activities/exercise. Suitable for: Running, hiking, walking	4046445EPw0000000P5
ErgoPad® ski & skate	Supportive foot orthoses for increased wearing comfort of sports shoes and for stabilizing the movement of the hindfoot during athletic activities/exercise. Suitable for: Alpine skiing, cross-country skiing, ice hockey, inline skating.	4046445EPss0000000MG
GloboTec® Junior	Orthopedic shell foot orthosis suitable for treating foot deformities in children and adolescents until their body growth is completed.	4046445GTJ00000000UR
GloboTec® comfort business	Orthopedic foot orthoses that are suitable for use in treating and preventing foot conditions.	4046445SES00000000Z9
GloboTec® comfort sports	Orthopedic foot orthoses that are suitable for use in treating and preventing foot conditions.	4046445GPcs0000000BW
ErgoPad® Soft	Orthopedic foot orthosis that is suitable for use in treating and preventing foot conditions. The viscoelastic soft foam cushions the foot and provides relief through redistribution of pressure.	4046445EPso0000000K4
Visco Balance®	Viscoelastic heel cushion for compensating leg length differences of 3, 5 or 10 mm. Thanks to the heel wedge, the product also serves to relieve the Achilles tendon.	4046445ViB00000000L5
Visco Heel K®	Viscoelastic heel cushion. It is used as a supination or pronation cushion. ViscoHeel K can be used for the targeted correction of varus or valgus misalignments of the heel bone as well as leg axis misalignments.	4046445ViK00000000SL
Visco Heel®	Viscoelastic heel cushion. It provides shock absorption and relief during load peaks. ViscoHeel can also be used for the redistribution of pressure and for pain reduction when treating pathologies in the heel and hindfoot areas.	4046445ViH00000000QF
Visco Ped®	Viscoelastic foot orthosis for providing pressure relief in the forefoot, midfoot and heel areas as well as for the gentle correction of static or dynamic misalignments of the foot's skeleton.	4046445ViP00000000W7


Visco Ped® S	Viscoelastic foot orthosis for providing pressure relief in the forefoot, midfoot and heel areas as well as for the gentle correction of static or dynamic misalignments of the foot's skeleton.	4046445ViPS0000000JG
Visco Spot®	Viscoelastic heel cushion. It provides shock absorption and relief during load peaks. ViscoSpot can also be used for the redistribution of pressure and for pain reduction when treating pathologies in the heel and hindfoot areas.	4046445ViS00000000YC
GloboPed® Mobil	Orthosis for providing the heel area with targeted relief.	4046445GPFM00000006Y
GloboPed® Postop	Orthosis for providing the forefoot and anterior metatarsal area with targeted relief.	4046445GPVA0000000BC
TRlactive OA	Orthopedic foot orthosis for providing support as well as relief in cases of foot axis misalignments and osteoarthritis of the knee.	4046445TRIOA0000000Z8

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