

EU declaration of conformity

(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

ANSCHRIFT
Bauerfeind AG
Triebeser Straße 16
07937 Zeulenroda-Triebes

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

LIEFERANSCHRIFT
Weißendorfer Straße 5
07937 Zeulenroda-Triebes

Bauerfeind AG
AG Jena HRB 206561

**VORSITZENDER
DES VORSTANDES**
Rainer Berthan

**MITGLIED
DES VORSTANDES**
Katharina Annamaria
Dietrich

**VORSITZENDER
DES AUFSICHTSRATES**
Prof. Rainer Kirchdörfer

BAUERFEIND.COM

declare in exclusive accountability, that our products:

Name	Intended purpose	Basic UDI-DI
AchilloTrain®	Support for the relief of Achilles tendon complaints with a friction pad and a heel wedge.	4046445AT1m00000006f
AirLoc®	Orthosis for stabilization of the ankle with movement limitation in pronation and supination, including unilaterally adjustable air cushioning	4046445AL000000000VM
CaligaLoc®	Orthosis for stabilization of the upper and lower ankle after serious injuries	4046445CaL000000000ZK
CoxaTrain®	Orthosis for joint stabilization and relief of pain in the hip joint for more movement with osteoarthritis of the hip	4046445CoT000000000L4
CerviLoc®	Orthosis for stabilization and relief of the cervical spine	4046445CL0000000000XK
CerviLoc® S	Orthosis for stabilization and relief of the cervical spine	4046445CLS000000000Q4
DorsoTrain®	Orthosis for active straightening and support of the spine	4046445DT00000000007V
EpiPoint®	Orthosis for targeted relief of the tendon insertions at the elbow	4046445EpP000000000L3
EpiTrain®	Support for the relief and stabilization of the elbow joint	4046445EpT000000000NX
GenuLoc®	Orthosis for immobilizing the knee joint – either with the leg extended or at a preset flexion angle	4046445GL00000000003J

GenuPoint®	Support for the relief and stabilization of the patellar tendon	4046445GP0000000076
GenuTrain®	Support for the activation, relief and stabilization of the knee joint	4046445GT00000000AS
GenuTrain® A3	Support for activation and stabilization in the cases of complex knee problems such as osteoarthritis	4046445A3000000007V
GenuTrain® OA	Orthosis providing targeted relief and stabilization for more movement with osteoarthritis of the knee	4046445GTOA00000009X
GenuTrain® P3	Support for centering and securing the patella with an adjustable corrective strap	4046445P3000000000NE
GenuTrain® S	Support for the guidance and stabilization of the knee joint using lateral splints	4046445GTS000000003B
GenuTrain SA	Support for the activation, relief and stabilization of the knee joint	4046445GTSA00000000CT
GenuTrain® S Pro	Support for increased stabilization of the knee joint using joint splints on the sides and restriction of range of motion	4046445GTSP00000000MQ
LordoLoc®	Orthosis for stabilization and relief of the lumbar spine using tensioning straps	4046445LoL000000000P3
LumboLoc®	Orthosis for the stabilization and relief of the lumbar spine	4046445LuL000000000UH
LumboLoc® Forte	Orthosis for increased stabilization and relief of the lumbar spine with a variable strap system	4046445LLF000000000PG
LumboLoc® Forte ES	Orthosis for increased stabilization and relief of the lumbar spine with a variable strap system and back pad	4046445LLFES00000000MH
LumboLoc® Forte SP	Orthosis for strong all-round stabilization and relief of the lumbar spine with large back pad and lateral pads	4046445LLFSP00000000U8
LumboLoc® Forte XT	Orthosis for increased stabilization and relief of the lumbar spine with a variable strap system and large back pad.	4046445LLFXT00000000ZB
LumboTrain® straight	The supports provide support for the back muscles for discomfort in the lumbar spine region.	4046445LTs00000000TK
LumboTrain® waisted	The supports provide support for the back muscles for discomfort in the lumbar spine region.	4046445LTw00000000WF
MalleoLoc®	Orthosis for increased stabilization of the upper and lower ankle	4046445MLL000000000UR
MalleoLoc® L	Orthosis for lateral stabilization of the ankle	4046445MLLL00000000CV

MalleoLoc® L3	Orthosis for lateral stabilization of the ankle - with elements that can be removed in three stages	4046445MLLL3000000EG
MalleoTrain®	Support for the relief and stabilization of the ankle	4046445MLT000000002L
MalleoTrain® S	Support for stabilization of the ankle joint thanks to a functional strap system	4046445MLTS0000000NS
MalleoTrain® S open heel	Support for stabilization of the ankle joint and for improved contact with the floor with an open heel	4046445MLTSoh000009K
MalleoTrain® Plus	Support used to provide increased stabilization and relief of the ankle thanks to a functional strap system.	4046445MLTP0000000LZ
ManuLoc®	Orthosis for stabilizing the wrist	4046445MnL00000000P5
ManuLoc® long	Orthosis for increased stabilization of the wrist	4046445MnLlo000000MN
ManuLoc® long Plus	Orthosis for immobilizing the wrist, parts of the forearm and the fingers with a removable finger support	4046445MnLloP000002C
ManuLoc® Rhizo	Orthosis for immobilization of the wrist with thumb brace	4046445MnLR0000000AT
ManuLoc® Rhizo long	Orthosis for immobilization of the wrist parts of the forearm with thumb brace.	4046445MnLRlo00000WR
ManuLoc® Rhizo long Plus	Orthosis for immobilizing the entire hand and forearm, with removable finger support and thumb brace	4046445MnLRloP00009H
ManuTrain®	Support for the relief and stabilization of the wrist	4046445MnT00000000UV
MOS-Genu	Orthosis for correction and stabilization after complex knee injuries or corrective osteotomy	4046445MOS000000004L
MyoTrain®	Support with adjustable compression for the treatment of thigh muscle injuries	4046445MyT000000006X
OmoTrain	Support for the relief and stabilization of the shoulder joint	4046445OmT00000000VW
OmoTrain S	Support for the relief and stabilization of the shoulder joint	4046445OmTS0000000J7
OmoLoc®	Orthosis for immobilization of the shoulder	4046445OmL00000000Q6
OmoLoc® 15	Orthosis for immobilization and relief of the shoulder	4046445OmL15000000TE
RhizoLoc®	Orthosis used for the stabilization the metacarpophalangeal and carpometacarpal joints of the thumb	4046445RzL000000006X
RhizoLoc® OA	Orthosis for the stabilization and relief of the carpometacarpal joint and metacarpophalangeal joint of the thumb.	4046445RzLOA000000Z9
SacroLoc®	Orthosis for the stabilization of the pelvis and targeted relief of the sacroiliac joints	4046445Sac00000000W4

SecuTec® Dorso	Orthosis for lordosis reduction and relief of the lumbar spine with bridging frame and corset stays	4046445ScD00000000D8
SecuTec® Omo	Orthosis for stabilizing and immobilizing the shoulder joint	4046445ScO00000000M5
SecuTec® Genu	Stabilizing orthosis that limits the range of motion in the case of complex knee injuries	4046445ScG00000000FD
SecuTec® Genu Flex	Stabilizing orthosis that limits the range of motion in the case of complex knee injuries.	4046445SCGX0000000E3
SecuTec® OA	Orthosis for relief and stabilization for osteoarthritis of the knee with leg axis misalignment	4046445ScOA0000000WM
SecuTec® Lumbo	Orthosis for lordosis reduction and relief of the lumbar spine with a bridging frame	4046445ScL00000000JY
SofTec® Coxa	Orthosis for the stabilization and guidance of the hip joint	4046445Cox00000000AG
SofTec® Dorso	Orthosis for increased stabilization of the thoracic and lumbar spine	4046445STD0000000046
SofTec® Genu	Orthosis for active and passive stabilization of the knee joint – ideal for long-term therapy	4046445STG000000006B
SofTec® Lumbo	Orthosis for immobilizing the lumbar spine with mobilization function with removable shell	4046445STL000000009W
SofTec® OA	Orthosis for the relief of medial osteoarthritis of the knee using adjustable air bladders	4046445OA000000000Z8
Spinova® Immo	Orthosis for immobilizing the lumbar spine	4046445Splm0000000VC
Spinova® Immo Plus	Orthosis for immobilizing the lumbar spine with mobilization function with removable shell	4046445SplmP000000DW
Spinova Immo Plus Classic	Orthosis for immobilizing the lumbar spine with mobilization function	4046445SplmPC00000M8
Spinova® Support Plus	Orthosis for stabilizing the lumbar spine with an anatomically contoured back pad	4046445SpSP0000000NA
Spinova® Support Plus Classic	Orthosis for moderately stabilizing the lumbar spine with an anatomically contoured back pad	4046445SpSPC000000XU
Spinova® Unload Plus	Orthosis for reducing and providing lordosis relief of the lumbar spine with removable bridging frame	4046445SpUP0000000PQ
Spinova® Unload Classic	Orthosis for moderately reducing and relieving lordosis of the lumbar spine with removable bridging frame	4046445SpUC0000000FZ
Spinova® Stabi Classic	Orthosis for moderately stabilizing the lumbar spine using corset stays	4046445SpStC000000JC
Spinova® Osteo	Orthosis for stabilization and active straightening of the spine, with free abdomen and chest area	4046445SpiO0000000ZW
Spinova® Osteo ES	Orthosis to stabilize the spine, limit sagittal movements and straighten the upper body.	4046445SpiOES00000SF

ValguLoc®	Orthosis for the correction of the big toe at rest	4046445VL000000000J3
ValguLoc® II	Orthosis for the correction of the big toe at rest and during movement	4046445VL200000000KH

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.

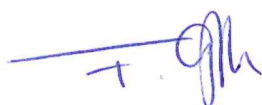
The products have been classified according to Annex VIII, Chapter III, MDR 2017/745 in risk class I.

They correspond to the given provisions of the Regulation (EU) 2017/745 for Medical Devices.

Zeulenroda-Triebes, 13th June 2024



Ines Exner
Person responsible for regulatory
compliance
Bauerfeind AG



p.o. Franziska Gerisch
Teamleader Regulatory Affairs EU
Bauerfeind AG