

## 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  
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SRN: . / .

declare under our sole responsibility that our products:

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BAUERFEIND.COM

| Product name      | Intended purpose   | Basic UDI-DI          |
|-------------------|--|-----------------------|
| AchilloTrain®     | Support for treating Achilles tendon problems  | 4046445AT0000000004Y  |
| AchilloTrain® Pro | Support for alleviating Achilles tendon problems using a friction pad  | 4046445ATP000000000T9 |
| AirLoc®           | Orthosis for stabilizing the upper ankle, with adjustable air cushions   | 4046445AL000000000VM  |
| CaligaLoc®        | Orthosis for stabilizing the upper and lower ankle after severe injuries   | 4046445CaL000000000ZK |
| CoxaTrain®        | Orthosis for providing joint stabilization and reduction of pain in the hip joint, to encourage increased activity in cases of 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 relief and stabilization of the elbow  | 4046445EpT000000000NX |
| GenuLoc®          | Orthosis for immobilizing the knee joint – extended or at a preset flexion angle   | 4046445GL00000000003J |
| GenuPoint®        | Support for relief and guidance of the patellar tendon   | 4046445GP000000000076 |
| GenuTrain®        | Support for activation, relief and stabilization of the knee joint   | 4046445GT0000000000AS |
| GenuTrain® A3     | Support for activation and stabilization in cases of complex knee problems such as osteoarthritis  | 4046445A300000000007V |

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| GenuTrain® OA            | Orthosis for targeted relief and stabilization to encourage increased activity in cases of osteoarthritis of the knee | 4046445GTOA00000009X |
| GenuTrain® P3            | Support for centering and securing the patella using an adjustable corrective strap                                   | 4046445P3000000000NE |
| GenuTrain® S             | Support for guidance and stabilization of the knee joint using splints on the sides                                   | 4046445GTS000000003B |
| GenuTrain® S Pro         | Support for increased stabilization of the knee joint using joint splints on the sides and restricted range of motion | 4046445GTSP0000000MQ |
| LordoLoc®                | Orthosis for stabilization and relief of the lumbar spine using tensioning straps                                     | 4046445LoL00000000P3 |
| LumboLoc®                | Orthosis for the stabilization and relief of the lumbar spine   | 4046445LuL00000000UH |
| LumboLoc® Forte          | Orthosis for increased stabilization and relief of the lumbar spine using an adjustable strap system                  | 4046445LLF00000000PG |
| LumboTrain®              | Support for stabilizing the back muscles in cases of problems in the lumbar region                                    | 4046445LT000000000FM |
| LumboTrain® Lady         | Support for stabilizing the back muscles in cases of problems in the lumbar region                                    | 4046445LTL0000000035 |
| MalleoLoc®               | Orthosis for increased stabilization of the upper and lower ankle   | 4046445MLL00000000UR |
| MalleoLoc® L             | Orthosis for lateral stabilization of the ankle   | 4046445MLLL0000000CV |
| MalleoLoc® L3            | Orthosis for lateral stabilization of the ankle – with elements that can be removed in three stages                   | 4046445MLLL3000000EG |
| MalleoTrain®             | Support for relief and stabilization of the ankle   | 4046445MLT000000002L |
| MalleoTrain® S           | Support for stabilizing the ankle using a functional strap system   | 4046445MLTS0000000NS |
| MalleoTrain® S open heel | Support for stabilizing the ankle and for improved contact with the ground thanks to an open heel                     | 4046445MLTSoh000009K |
| MalleoTrain® Plus        | Support for increased stabilization and relief of the ankle using a functional strap system                           | 4046445MLTP0000000LZ |
| ManuLoc®                 | Orthosis for immobilizing the wrist   | 4046445MnL00000000P5 |
| ManuLoc® long            | Orthosis for immobilizing the wrist and parts of the forearm  | 4046445MnLlo000000MN |
| ManuLoc® long Plus       | Orthosis for immobilizing the wrist, parts of the forearm and of the fingers, with removable finger support           | 4046445MnLloP000002C |
| ManuLoc® Rhizo           | Orthosis for immobilizing the wrist, with thumb brace   | 4046445MnLR0000000AT |
| ManuLoc® Rhizo long      | Orthosis for immobilizing the wrist and 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 relief and stabilization of the wrist   | 4046445MnT00000000UV |

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| 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 relief and stabilization of the shoulder joint  | 4046445OmT00000000VW  |
| OmoTrain S                    | Support for relief and stabilization of the shoulder joint  | 4046445OmTS00000000J7 |
| OmoLoc®                       | Orthosis for immobilizing the shoulder  | 4046445OmL00000000Q6  |
| RhizoLoc®                     | Orthosis for stabilizing the metacarpophalangeal and carpometacarpal joints of the thumb                | 4046445RzL000000006X  |
| SacroLoc®                     | Orthosis for stabilization of the pelvis and targeted relief of the sacroiliac joints                   | 4046445Sac00000000W4  |
| SecuTec® Dorso                | Orthosis for lordosis reduction and relief of the lumbar spine using a bridging frame and corset stays  | 4046445ScD00000000D8  |
| SecuTec® Omo                  | Orthosis for stabilizing and immobilizing the shoulder joint  | 4046445ScO00000000M5  |
| SecuTec® Genu                 | Orthosis for stabilization with restricted range of motion in cases of complex knee injuries            | 4046445ScG00000000FD  |
| SecuTec® OA                   | Orthosis for relief and stabilization in cases of osteoarthritis of the knee with leg axis misalignment | 4046445ScOA00000000WM |
| SecuTec® Lumbo                | Orthosis for lordosis reduction and relief of the lumbar spine using 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 support and treatment of the knee joint  | 4046445STG000000006B  |
| SofTec® Lumbo                 | Orthosis for immobilizing the lumbar spine, with mobilization function thanks to the removable shell    | 4046445STL000000009W  |
| SofTec® OA                    | Orthosis for relief in cases of medial osteoarthritis of the knee using adjustable air bladders         | 4046445OA00000000Z8   |
| Spinova® Immo                 | Orthosis for immobilizing the lumbar spine  | 4046445SpIm00000000VC |
| Spinova® Immo Plus            | Orthosis for immobilizing the lumbar spine, with mobilization function thanks to the removable shell    | 4046445SpImP0000000DW |
| Spinova Immo Plus Classic     | Orthosis for immobilizing the lumbar spine, with mobilization function                                  | 4046445SpImPC000000M8 |
| Spinova® Support Plus         | Orthosis for stabilizing the lumbar spine, with anatomically contoured back pad                         | 4046445SpSP00000000NA |
| Spinova® Support Plus Classic | Orthosis for moderate stabilization of the lumbar spine, with anatomically contoured back pad           | 4046445SpSPC0000000XU |
| Spinova® Unload Plus          | Orthosis for lordosis reduction and increased relief of the lumbar spine, with removable bridging frame | 4046445SpUP00000000PQ |



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| Spinova® Unload Classic | Orthosis for moderate lordosis reduction and relief of the lumbar spine, with removable bridging frame     | 4046445SpUC0000000FZ  |
| Spinova® Stabi Classic  | Orthosis for moderate stabilization of the lumbar spine using corset stays                                 | 4046445SpStC0000000JC |
| Spinova® Osteo          | Orthosis for stabilization and active straightening of the spine, with unobstructed abdomen and chest area | 4046445SpiO0000000ZW  |
| ValguLoc®               | Orthosis for the correction of the big toe at rest   | 4046445VL00000000J3   |
| 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 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



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