

Die IT-V Medizintechnik GmbH erklärt in alleiniger Verantwortung die Konformität der folgenden Medizinprodukte mit der **EU-Verordnung 2017/745** vom 05. April 2017.

*IT-V Medizintechnik GmbH declares sole responsibility for the conformity of the following medical devices with **EU Regulation 2017/745** of 05 April 2017.*

Produktmodell <i>Device model</i>	Basis UDI-DI <i>Basic UDI-DI</i>
WingSTEP Systems	91200743915LY
Pillows PU	91200743920LR
PU Cover	91200743925M3
MCT Wedge	91200743930LU
Indexing Adapter	91200743935M6
Thermoplastic Masks	91200743938MC
Indexing Bars	91200743940LX
Wall Holder	91200743946MB
Handlebars	91200743949MH
Elevation Barrels	91200743950M2
Mask Adapter	91200743965MF
Elevation Blocks	91200743933M2



Zweckbestimmung:

Der WingSTEP dient zur Positionierung des Lungen- und Thoraxbereichs des Patienten während der Strahlentherapie und Diagnostik.

Intended Use:

The WingSTEP is intended for positioning of the lung- and thorax area of the patient during radiotherapy and diagnostics.

Risikoklasse:

Risk classification:

I gemäß Anhang VIII, Kapitel III, Regel 1

I according to Annex VIII, Chapter III, Rule 1

Angewandte Normen:

Applied Standards:

EN ISO 14971: 2019

OVE EN 62366-1: 2017

DIN EN ISO 10993-1: 2021

ISO 20417: 2021

EN ISO 15223-1: 2017

EN ISO 13485: 2016

Die genannten Produkte erfüllen die Konformität mit allen anwendbaren Punkten der oben genannten Normen.

The mentioned products fulfill the conformity with all applicable points of the standards mentioned above.

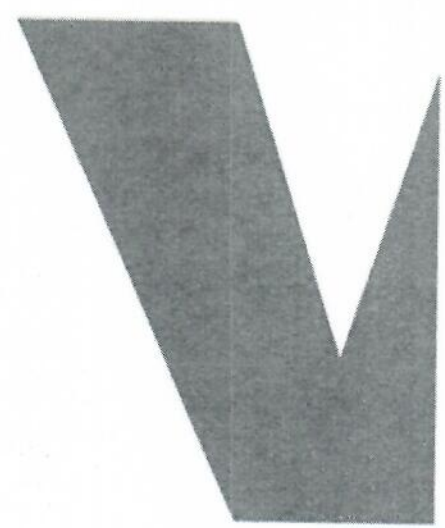
Diese Konformitätserklärung ist gültig ab Ausstellungsdatum bis **10.02.2025**.
*This declaration of conformity is valid from the date of issue until **10.02.2025**.*

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Markus Völp, CEO

Innsbruck, 09.02.2022

Declaration of Conformity

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Anhang zur Konformitätserklärung DoC_WS_V6
Attachment to Declaration of Conformity DoC_WS_V6Nur gültig in Verbindung mit Seite 1 & 2.
*Only valid in connection with page 1 & 2.***Produkte des Produktmodells WingSTEP Systems:**
Products connected to product model WingSTEP Systems:

	Produktnummer Product number	UDI-DI
System WingSTEP Low - Pin Joint	P10107-740	9120074397408
System WingSTEP High - Pin Joint	P10107-741	9120074397415
System WingSTEP Low - Ball Joint	P10107-742	9120074397422
System WingSTEP High - Ball Joint	P10107-743	9120074397439
System WingSTEP High HS IMRT - Ball Joint	P10107-744	9120074397446
System WingSTEP High for Varian - Ball Joint	P10107-745	9120074397453
System WingSTEP Low for Varian - Ball Joint	P10107-746	9120074397460
System WingSTEP Carbon High - Ball Joint	P10107-747	9120074397477
System WingSTEP Carbon Low - Ball Joint	P10107-749	9120074397491
System WingSTEP Carbon High - Pin Joint	P10107-750	9120074397507
System WingSTEP Carbon Low - Pin Joint	P10107-751	9120074397514
System WingSTEP MR - Low - Ball Joint	P10107-753	9120074397538
System WingSTEP MR - High - Ball Joint	P10107-754	9120074397545
System WingSTEP US Low	P10107-770	9120074397705
System WingSTEP US High	P10107-771	9120074397712

Produkte des Produktmodells Pillows PU:
Products connected to product model Pillows PU:

	Produktnummer Product number	UDI-DI
Pillow Standard Blue A	P10107-240	9120074392403
Pillow High Blue B	P10107-241	9120074392410
Pillow Wide A	P10107-267	9120074392670
Pillow Tilt Wide G	P10107-268	9120074392687

Produkte des Produktmodells PU Cover:
Products connected to product model PU Cover:

	Produktnummer Product number	UDI-DI
PU Cover for Arm Support (2 pcs.)	P10107-242	9120074392427
PU Cover for Wrist Support (2 pcs.)	P10107-243	9120074392434

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Produkte des Produktmodells MCT Wedge:
Products connected to product model MCT Wedge:

	Produktnummer <i>Product number</i>	UDI-DI
MCT Wedge 10°	P10107-440	9120074394407
MCT Wedge evo Indexed	P10107-478	9120074394780
MCT Wedge 5°	P10107-512	9120074395121
MCT Wedge 15°	P10107-513	9120074395138

Produkte des Produktmodells Indexing Adapter:
Products connected to product model Indexing Adapter:

	Produktnummer <i>Product number</i>	UDI-DI
MCT Wedge Indexing Adapter	P10107-474	9120074394742

Produkte des Produktmodells Thermoplastic Masks:
Products connected to product model Thermoplastic Masks:

	Produktnummer <i>Product number</i>	UDI-DI
iCAST Chin Double Micro 4mm	P10107-334	9120074393349

Produkte des Produktmodells Indexing Bars:
Products connected to product model Indexing Bars:

	Produktnummer <i>Product number</i>	UDI-DI
MCT Wedge Indexing Bar for Elekta	P10107-475	9120074394759
MCT Wedge Indexing Bar for Varian	P10107-476	9120074394766
MCT Wedge Indexing Bar for Pin Indexing	P10107-477	9120074394773

Produkte des Produktmodells Wall Holder:
Products connected to product model Wall Holder:

	Produktnummer <i>Product number</i>	UDI-DI
Wall holder for WS	P10107-446	9120074394469

Produkte des Produktmodells Handlebars:
Products connected to product model Handlebars:

	Produktnummer <i>Product number</i>	UDI-DI
WingSTEP Pole Bar	P10107-487	9120074394872
WingSTEP Pole Bridge Bar (add on system)	P10107-522	9120074395220

Produkte des Produktmodells Elevation Barrels:

Products connected to product model Elevation Barrels:

	Produktnummer <i>Product number</i>	UDI-DI
WingSTEP Arm Support Elevation Barrel	P10107-488	9120074394889

Produkte des Produktmodells Mask Adapter:

Products connected to product model Mask Adapter:

	Produktnummer <i>Product number</i>	UDI-DI
HeadSTEP Upper Plate for WingSTEP	P10107-467	9120074394674

Produkte des Produktmodells Elevation Blocks:

Products connected to product model Elevation Blocks:

	Produktnummer <i>Product number</i>	UDI-DI
WingSTEP Elevation Block ABS	P10107-452	9120074394520

Declaration of Conformity

