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EU Declaration of Conformity for Medical Devices

This is a Declaration of Conformity made under Article 19 of Regulation MDR 2017/745/EU.

Manufacturer:	TRUMPF Medizin Systeme GmbH + Co. KG
Business Address:	Carl-Zeiss-Str. 7-9 07318 Saalfeld Germany
Single Registration Number:	Not available
Product Description	PST 300 Mobile Operating Table PST 300 Orthopedic Extension PST 300 Pad
Product Name/ Reference Number:	PST 300 Mobile Operating Table: PST 300L / 2072782 PST 300S / 2072783 PST 300L EU / 2072784 PST 300S EU / 2072785 PST 300 Orthopedic Extension: PST 300 Extension Adapter / 2072419 PST 300 Pad: PST 300L B Pad / 2071905 PST 300S B Pad / 2071906
Classification:	Class I (under Clause 7 of Article 52 to the Regulation 2017/745/EU)
GMDN Code and Term:	PST 300 Mobile Operating Table: 33152 Universal Operating Table, Electromechanical PST 300 Orthopedic Extension: 42308 Orthopedic Extension / Accessories for Spine PST 300 Pad: 31684 Operating Table Pad, Reusable
UMDNS Code:	PST 300 Mobile Operating Table: 13-961 PST 300 Orthopedic Extension: 13-967 PST 300 Pad: 12-478

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Basic-UDI-DI:	PST 300 Mobile Operating Table: 0887761GMN000086UQ PST 300 Orthopedic Extension: 0887761GMN000019U9 PST 300 Pad: 0887761GMN000005TW
Valid for:	Products to which the declaration of conformity procedures applies this may include all batches, lots or serial numbers
Valid until:	16 April 2025

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential requirements and the classification rules before being supplied.

Standards applied:	See attached schedule for multiple standards
Common Specifications applied:	Not applicable

We declare in sole responsibility, that the products relevant, including accessories and components, have been developed, manufactured, and tested in accordance with the pertinent provisions of

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restrictions of use of certain hazardous substances in electrical and electronic equipment

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)

Regulation (EC) No1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment

Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility

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Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EWG

This declaration shall be void whenever the medical device is used contrary to the intended purpose, and when any modification is made to the medical device without prior approved by the manufacturer.

CE

Saalfeld, 2020-Apr-17

Sandro List
Authorized Representative

Florian Denk
Director Quality Assurance

Appendix:

Following table includes all standards applied:

Product related standards:	EN 1041	Information supplied by the manufacturer of medical devices.
	EN ISO 15223-1	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
	IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
	EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	EN ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
	EN ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
	IEC 60601-2-46	Medical Electrical Equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables
	EN ISO 19054	Rail systems for supporting medical equipment
Others:	EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
	EN ISO 14971	Medical devices - Application of risk management to medical devices
	IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
	IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
	IEC 62304	Medical device software - Software life-cycle processes
	IEC 60601-1-9	Requirements for environmentally conscious design
	EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Following table includes all common specifications applied:

Product related common specifications:	Not applicable

Document type: FORM

Starting document at Trumpf Medical: 103185

General Notes

Before using the document, make sure you are using the latest version
and that you are trained to use the document. Should you require training, please contact your manager and training coordinator.

- **Scope:** This form sheet applies to Trumpf Medical Puchheim, Saalfeld and Taicang.

1 Purpose

To define the general procedure for Trumpf Medical Device and Accessories to be conform with the Regulation euMDR 2017/745/EU and to be able to enter the EU market.

2 Other applicable documents

Doc. No./Ref.	Title
103185	euMDR Product Conformity Process

3 Change history

Version	Author	Change
01	Jonathan von Wittern	Initialization
02	Jonathan von Wittern	Listing common specification and name of NB in case an NB was implicated