



Total Healthcare Innovation GmbH

DECLARATION OF CONFORMITY
(Directive 93/42/EEC)

MD IO 5.1_DoC_SPS

Rev. 11

page 1 of 1

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This declaration of conformity is issued under the sole responsibility of THI Total Healthcare Innovation GmbH.

The company declares that the medical device system **SPS Sterile Head Belt System**, consisting of components and accessories shown in the table in this statement is in compliance with the relevant Community harmonization legislation: **Directive 93/42/EEC**.

Where applicable, compliance with essential requirements has been confirmed by: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany, Tel.: +496995427, Identification Number: 0297.

Certificate Registration No: 489169 MR2
 Certificate No: 170689495

Name	REF	Use	Sterilization	Class	Rule	Annex	CE Mark
SPS – Head Belt System (XS – XL)	SP100	Non sterile, reusable	-	I	1	VII	CE
SPS – Head Belt System (M – 4XL)	SP101	Non sterile, reusable	-	I	1	VII	CE
Foam Kit - SPS	SP774	Non sterile, reusable	-	I	1	VII	CE
SPS - Sterile Protection Shield	SP250	STERILE, single use	EO	Is	4a	II	CE ₀₂₉₇
BATTERY PACK	60401	Non sterile, reusable	-	I	1	VII	CE
BATTERY CHARGER	60500	Non sterile, reusable	-	I	1	VII	CE

The following harmonized standards have been used as applicable:

ISO 14971:2013; EN 62079:2002; DIN EN ISO 11135-1:2012, EN ISO 11731-1:2006; EN 10993-7:2008; EN 13795:2001+A1:2013, ÖVE/ÖNORM EN 60601-1, ÖVE/ÖNORM EN 60601-1-2, UN 3480/3481, UL2054, EN55011, EN61000, CISPR11

This declaration of conformity is valid until 2023-02-01

Issue place and date: Feistritz im Rosental, 2019-11-04



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