



Total Healthcare Innovation GmbH

**DECLARATION OF CONFORMITY**  
(Directive 93/42/EEC)

MD IO 5.1\_DoC\_OXY-AERO

Rev. 09

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**Company:** THI Total Healthcare Innovation GmbH  
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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 **OXYGEN AEROLYTE System** consisting of components and devices 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

<u>Name</u>	<u>REF</u>	<u>Use</u>	<u>Sterilization</u>	<u>Class</u>	<u>Rule</u>	<u>Annex</u>	<u>CE Mark</u>
OXYGEN Aerolyte - Helmet (XS – XL)	70100	Non sterile, reusable	-	I	1	VII	CE
OXYGEN Aerolyte - Helmet (M – 4XL)	70110	Non sterile, reusable	-	I	1	VII	CE
OXYGEN Aerolyte - LED light Helmet (XS – XL)	70120	Non sterile, reusable	-	I	1	VII	CE
OXYGEN Aerolyte - LED light Helmet (M – 4XL)	70130	Non sterile, reusable	-	I	1	VII	CE
BATTERY PACK	60401	Non sterile, reusable	-	I	1	VII	CE
OXYGEN - BATTERY CHARGER	60500	Non sterile, reusable	-	I	1	VII	CE
OXYGEN - Sterile Lens Hood	60200.01	STERILE, single use	EO	Is	4a	II	CE <sub>0297</sub>
OXYGEN - Sterile TOGA (XL – XXL)	60220.01	STERILE, single use	EO	Is	4a	II	CE <sub>0297</sub>
OXYGEN - Sterile TOGA (M – L)	60221.01	STERILE, single use	EO	Is	4a	II	CE <sub>0297</sub>
OXYGEN - Sterile TOGA (XXS – S)	60222.01	STERILE, single use	EO	Is	4a	II	CE <sub>0297</sub>



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## DECLARATION OF CONFORMITY

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The following harmonized standards have been used as applicable:

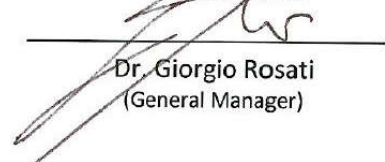
EN 556-1:2001/AC:2006, EN 14971:2012, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-7:2008/AC:2009, EN ISO 11607-1:2009+A1:2014, EN ISO 11607-2:2006 +A1:2014, EN ISO 11135:2014, EN 13795:2001+A1:2013, EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 62366-1:2015 +COR1:2016, IEC 62133:2012

This declaration of conformity is valid until 2023-02-21

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



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Dr. Giorgio Rosati  
(General Manager)