

 Total Healthcare Innovation GmbH	DECLARATION OF CONFORMITY ViVi® gowns	MD IO 5.1_DoC_ViVi®_MDR_Class Is Rev. 18 page 1 of 4
--	--	--

DECLARATION OF CONFORMITY

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

The manufacturer declares, under its sole responsibility, that the products covered in this document are in conformance with the Medical Devices Regulations (EU) 2017/745 and with the Personal Protective Equipment Regulation (EU) 2016/425

Manufacturer Name	THI Total Healthcare Innovation GmbH
Manufacturer Address	Gewerbestraße 4 9181 Feistritz im Rosental, Austria
SRN	AT-MF-00044495
Phone	+43 4228 30100-0
Fax:	+43 4228 30100-20
E-Mail:	office@thigmbh.at
Website:	www.thigmbh.at
System intended use: The ViVi® System is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to help protect against contamination and/or exposure to infectious body fluids and harmful microorganisms towards the patient and the surgical personnel. The products in the table shown in Annex I are elements of ViVi® System .	
Notified Body	DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany Tel.: +49 6995427, Identification Number: 0297
Classification	Class Is, Rule 4(a) within Annex VIII of the Regulation.
Conformity Assessment Route	Annex IX, Chapter I and III
Certificate ID and certificate registration no.	1000255315 / 489169 MDR2017Q
Common Specifications / Standards Applied	EN ISO 13485:2016 + AC 2018 + A11:2021; EN ISO 14971:2019 + A11:2021; EN ISO 20417:2021; EN ISO 15223-1:2021; EN 556-1:2024; EN 868-5:2018; EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2003; EN ISO 11607-1:2019; EN ISO 11135:2014 + A1:2019; EN 13795-1:2019; ASTM D4169-23e1; ASTM F1980-21; ASTM F2407_F2407M-23A;

 Total Healthcare Innovation GmbH	DECLARATION OF CONFORMITY ViVi® gowns	MD IO 5.1_DoC_ViVi*_MDR_Class Is Rev. 18 page 2 of 4
---	--	--

Name	Karl Hintermann
Title	Quality Manager
Signature	  THI-Total Healthcare Innovation GmbH Gewerbestrasse 4
Place of Issuance	Feistritz im Rosental, Austria Tel: +43 (0) 4228 30 100-0, Fax +43 (0) 4228 30 100-50 Email: office@thigmbh.at
Date	27-jan-2020



Total Healthcare Innovation GmbH

DECLARATION OF CONFORMITY

ViVi® gowns

MD IO 5.1_DoC_ViVi®_MDR_Class Is

Rev. 18

page 3 of 4

Annex I.

Name	REF	Basic UDI-DI	Use	Sterilization	Class	Rule	Annex	CE Mark
ViVi® HOOD	80200	9009607GOWNS80XXXD4	STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® HOOD¹</i>	<i>80200V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® HOOD	80210		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
ViVi® HOOD HFD	80301		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® HOOD HFD¹</i>	<i>80301V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi®PEEL-OFF HOOD	80500		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi®PEEL-OFF HOOD¹</i>	<i>80500V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® TOGA XL-XXL	80220	9009607GOWNS80XXXD4	STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® TOGA XL-XXL¹</i>	<i>80220V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® TOGA M-L	80221		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® TOGA M-L¹</i>	<i>80221V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® TOGA XXS-S	80222		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® TOGA XXS-S¹</i>	<i>80222V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® TOGA PREMIUM XL-XXL	82220	9009607GOWNS82XXXDJ	STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® TOGA PREMIUM XL-XXL¹</i>	<i>82220V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® TOGA PREMIUM M-L	82221		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® TOGA PREMIUM M-L¹</i>	<i>82221V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® TOGA PREMIUM XXS-S	82222		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® TOGA PREMIUM XXS-S¹</i>	<i>82222V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® TOGA PREMIUM 3XL	82223		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® TOGA PREMIUM 3XL¹</i>	<i>82223V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>



Total Healthcare Innovation GmbH

DECLARATION OF CONFORMITY

ViVi® gowns

MD IO 5.1_DoC_ViVi®_MDR_Class Is

Rev. 18

page 4 of 4

Name	REF	Basic UDI-DI	Use	Sterilization	Class	Rule	Annex	CE Mark
ViVi® PULL-OVER TOGA XL-XXL	80230	9009607GOWNS80XXXXD4	STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® PULL-OVER TOGA XL-XXL¹</i>	<i>80230V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® PULL-OVER TOGA M-L	80231		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® PULL-OVER TOGA M-L¹</i>	<i>80231V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® PULL-OVER TOGA XXS-S	80232		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® PULL-OVER TOGA XXS-S¹</i>	<i>80232V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® PEEL-OFF TOGA PREMIUM XL-XXL	82520	9009607GOWNS82XXXXDJ	STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® PEEL-OFF TOGA PREMIUM XL-XXL¹</i>	<i>82520V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® PEEL-OFF TOGA PREMIUM M-L	82521		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® PEEL-OFF TOGA PREMIUM M-L¹</i>	<i>82521V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® PEEL-OFF TOGA PREMIUM XXS-S	82522		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® PEEL-OFF TOGA PREMIUM XXS-S¹</i>	<i>82522V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>
ViVi® PEEL-OFF TOGA PREMIUM 3XL	82523		STERILE, single use	EO	Is	4(a)	VIII	CE ₀₂₉₇
<i>ViVi® PEEL-OFF TOGA PREMIUM 3XL¹</i>	<i>82523V</i>		<i>STERILE, single use</i>	<i>EO</i>	<i>Is</i>	<i>4(a)</i>	<i>VIII</i>	<i>CE₀₂₉₇</i>

¹ Variant with customer logo