

<b>EC Declaration of Conformity</b>		
Document Title	Document Description	Version
<b>101-5000-13</b>	<b>Class IIa EMDN and GMDN Codes</b>	<b>2</b>

We, World Class Technology Corporation, declare under our sole responsibility that the Orthodontic Elastomerics described in the table below conform with the Essential Requirements of the Medical Device Directive (MDD) 93/42/EEC and its amendments, following the Annex V conformity assessment route.

EMDN Code	EMDN Description	GMDN Code	GMDN Description	Classification
Q010404	Orthodontic Elastics, Chains and Springs	31797	Orthodontic Spring	IIa
		62073	Orthodontic inter-bracket elastic chain	IIa
		62074	Orthodontic inter-arch elastic band	IIa
Q010406	Orthodontic Ligatures	41677	Orthodontic archwire/bracket ligature	IIa
Q010402	Orthodontic Bands	38734	Orthodontic Metal Band	IIa
Q010403	Orthodontic Brackets and Buttons	46581	Orthodontic bracket, metal	IIa
		58818	Self-ligating orthodontic bracket	IIa
		31759	Orthodontic Tube	IIa
Q010405	Orthodontic Wires	41397	Orthodontic archwire	IIa
Q010499	Orthodontic Devices - Other	38741	Orthodontic Lock	IIa

The technical file for these devices is maintained at World Class Technology Corporation at the address listed below. The authorized representative located within the Community is mdi Europa GmbH at the address listed in the table below.

<b>MANUFACTURER</b>		
Name of Company	Address	Telephone/fax/email
World Class Technology Corporation	1300 NE Alpha Drive McMinnville, OR 97128 USA	Phone: 503-472-8320 Email: info@worldclasstech.com
UDI-DI	Company code + date of manufacture + lot code	
SRN	US-MF-000014389	

<b>AUTHORIZED REPRESENTATIVE</b>			
Name of Company	Address	SRN	Telephone/fax/email
MDI Europa	Langenhagener STR. 71 30855 Langenhagen Germany	DE-AR-000006218	phone: +49-511-3908 9530 fax: +49-511-3908 9539 email: info@mdi-europa.com

<b>UK RESPONSIBLE PERSON</b>		
Name of Company	Address	Telephone/email
Qserve Group UK, Ltd.	49 Greek Street W1D 4EG, Soho, London United Kingdom	+44 7408 830172 info@qservegroup.com

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NOTIFIED BODY			
Name of Company	Address	NB Number	Telephone/fax/email
TUV Rheinland LGA Products GMBH	Tillysrasse 2, 90431 Nurnberg, Germany	0197	Phone: +49-911-655 5525 Fax: +49-911-655 5526 Email: service@de.tuv.com

World Class Technology Corporation, located at 1300 NE Alpha Drive, McMinnville, Oregon 97128 USA, declares under its sole responsibility that the listed UMDNS and GMDN codes are used to reference WCT Medical Devices that comply with the general safety and performance requirements following the Annex V Conformity Assessment Route of the EU MDD 93/42/EEC. The results of the design, development and manufacturing activities are registered under the applicable Annex V requirements of the MDD 93/42/EEC, registration number DD 2234074-1, expiry date 2024-05-26.

We hereby appoint, mdi Europa GmbH to act as European Authorized Representative according to the provisions of Article 11 of the EU Medical Device Regulation, 2017/745.

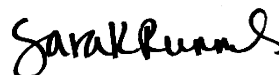
These products also comply with the ISO 13485 Standard. All applicable verification and validation activities, including the Risk Assessment Process, were conducted as described in ISO 14971.

Signed for and on behalf of World Class Technology Corporation in McMinnville, Oregon:

**COMPANY REPRESENTATIVE:** Sara Runnels

**TITLE:** Regulatory Affairs

**SIGNATURE:**



**PLACE:** McMinnville, Oregon, USA

**DATE:** 2023.10.03

# 101-5000-13 (DOC-335) Ver. 2

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**Approved By:**

[\(CO-250\) Update Title to 101-5000-13](#)

**Description**

Changing title to EU Declaration of Conformity - Class IIa EMDN and GMDN Codes. Please refer to change order form in Evaluation tab for more information.

**Justification**

Removed UMDNS codes and using EMDN instead.

<b>Assigned To:</b>	<b>Initiated By:</b>	<b>Priority:</b>	<b>Impact:</b>
Maureen Janssen	Maureen Janssen	Medium	Minor

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**Version History:**

<b>Author</b>	<b>Effective Date</b>	<b>CO#</b>	<b>Ver.</b>	<b>Status</b>
Maureen Janssen	October 17, 2023 6:18 AM PDT	<a href="#">CO-250</a>	2	Published
Maureen Janssen	August 10, 2023 7:54 AM PDT	<a href="#">CO-204</a>	1	Superseded
Maureen Janssen	November 23, 2022 9:45 AM PST	<a href="#">CO-29</a>	0	Superseded