

EC Declaration of Conformity		
Document Title	Document Description	Version
101-5000-03	Class I EMDN and GMDN Codes	1

We, World Class Technology Corporation, declare under our sole responsibility that the Orthodontic Instruments described in the table below conform with the requirements of the Medical Device Regulation (MDR) 2017/745 and its amendments, following the Annex VIII conformity assessment route, based on classification per Annex Rule 5.

EMDN Code	EMDN Description	GMDN Code	GMDN Description	Classification
Q010499	Orthodontic Devices, Other	33209	Orthodontic Pliers	I
Q010499	Orthodontic Devices, Other	62086	Self-Ligating orthodontic bracket open/close tool.	I
Q010599	Dental Instruments, Single-Use Other	31799	Orthodontic Appliance Dimension Gauge	I
Q010599	Dental Instruments, Single-Use Other	62072	Orthodontic Elastomeric Appliance Pusher	I
Q010501	Dental Burs and abrasive disks, single-use	35807	Interproximal reduction kit	I

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.

MANUFACTURER		
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	

AUTHORIZED REPRESENTATIVE			
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

UK RESPONSIBLE PERSON		
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

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

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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 of Annex I of the EU Medical Device Regulation, 2017/745.

We have appointed 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 BS EN ISO 13485, EN ISO 15233-1, BS EN 20417 and EN 1641 harmonized standards. All applicable verification and validation activities, including the Risk Assessment Process, were conducted as described in EN 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: 2023.08.01

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Approved By:

[\(CO-204\) Update GMDN and added EDMN on DoC](#)

Description

Update GMDN codes, removed UMDNS, and added EDMN on Declarations of Conformity. Please refer to change order form in Evaluation Tab for more information.

Justification

Updated codes.

Assigned To:

Maureen Janssen

Initiated By:

Maureen Janssen

Priority:

Medium

Impact:

Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Maureen Janssen	August 10, 2023 7:54 AM PDT	CO-204	1	Published
Maureen Janssen	November 23, 2022 9:45 AM PST	CO-29	0	Superseded