EC Declaration of Conformity

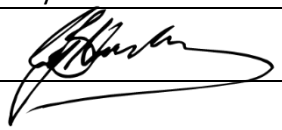
In accordance with the following regulation

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	**Metrodent Dental Waxes**
Legal Manufacturer: (Name on Label)	**Metrodent Limited** Lowergate Works Lowergate, Paddock Huddersfield. HD3 4EP. UK
Manufacturers SRN:	UK-MF-000036947
Basic UDI-DI:	506092449METROWAX8Q
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Dental Wax for bite registration and trial wax dentures
MDR Classification:	Class I according to rule 5 of Annex VIII of EU MDR 2017/745
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	**MT-AR-000000234**
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name Garry Needham **Position** Managing Director

Signed  **Date** 5th Oct 2023 **Place** Huddersfield

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012 / ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
EN ISO 10993-23:2021	Biological evaluation of medical devices Part 23: Tests for irritation

Appendix II – Product Listing/Schedule

Catalogue Number	Device Name	GMDN Code
1WAX…	Metro Modelling Wax No.1	63983
2WAX…	Metro Modelling Wax No.2	63983
4WAX…	Metro Modelling Wax No.4	63983
6WAX…	Metro Modelling Wax No.6	63983
8WAX…	Metro Modelling Wax No.8	63983
7WAX…	Metro Modelling Wax Metromorphic	63983
LPWAX…	Metro Modelling Wax Light Pink	63983
CWAX…	College Wax	63983
WAXBB…	Metro Bite Blocks	38602
WUS	Wax Up Sticks	63983
RWAX	Ribbon Wax	38584
SRBW	Soft Bite Wax	38584
SWAX	Strip Wax	38584
GWAX…	Gnathic Modelling Wax	63983
GWAXBB…	Gnathic Bite Blocks	38602

Version History

Version	Compiled by	Date	Description
1.0	Garry Needham	11/10/2021	EC Declaration of Conformity MDR
1.1	Matthew Needham	01/12/2021	Added ISO 7405 and ISO 10993 standards
1.2	Matthew Needham	05/10/2023	Added SRN