



# EU Declaration of Conformity

DentalOrganiser Ltd

Legal manufacturer: name	DentalOrganiser Ltd
Legal manufacturer: address	Garrynagry, Roscahill, Galway, H91V8C5, Ireland
Eudamed SRN:	IE-MF-000043529
Product name	VisionButler Lip and Cheek Retractor
GMDN code and description	44828 Dental cheek retractor, professional, reusable
EMDN code and description	Q010104 Dental procedure devices; various
Basic UDI DI	539152815VisionButYF
Product code / Catalogue number	VISBURBL.MS – Medium VISBURBL.L - Large
Classification	Class I
Conformity Assessment Route	Annex IX (§1, 2 & 3) of EU Medical Devices Regulation (EU) 2017/745

This Declaration of Conformity is issued under the sole responsibility of  
DentalOrganiser Ltd

We hereby declare that the product listed above meets the provisions of EU  
Medical Device Regulation (EU) 2017/745.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Name:

Dr Paul Moore

Position:

CEO

Place of issue:

Galway, Ireland

Date:

28 June 2024