

Name of manufacturer: **Topdental (Products) Ltd.**
 Address of manufacturer: **12 Ryefield Way, Silsden, Keighley,
 West Yorkshire, BD20 0EF, UK.**
 SRN: **GB-MF-000003937**
 Authorised Representative: **Directa AB, Box 723, Finvids väg 8,
 SE-194 27 Upplands Väsby, Sweden.**
 SRN: **SE-AR-000002492**
 Risk Class: **Class I**
 Declaration date: **26th May 2021**



Product Name (Inc Trade name)	Intended Use	Product Codes	Classification Rule Number	Basic UDI-DI
Polydent Universal Handpiece Oil Spray	All-purpose hand piece lubricant spray for maintenance of all dental hand pieces including high speed, slow speed and air motors.	1899-001	Rule 1	15060493850i18N

- This EU declaration of conformity is issued under the sole responsibility of the manufacturer.
- The above-mentioned devices meet the provisions of Regulation EU MDR 2017/745 of 5th April 2017 concerning medical devices.
- The above-mentioned devices have been classified as class I according to Annex VIII.
- The Notified Body has assessed the conformity of medical devices and audited Topdental Products Quality Assurance system which meets the requirements of ISO 13485:2016.
- Referenced technical documentation is retained under the premises of the manufacturer.

Daniel Rollen
 Managing Director
 Place of Issue: Silsden UK

Miranda Armstrong
 Quality Manager
 Place of Issue: Silsden UK

docTPH1 v1.0 260521