EU Declaration of Conformity

Manufacturer :	**Gouka B.V.**
Adress:	Prinses Mariestraat 13, 2514 KC, The Hague The Netherlands
Single Registration Number (SRN) :	NL-CA-058
Basic-UDI :	08720892840905
Names of the device :	**Dentigel 0,4% fluoride**
Classification :	Class I, Rule 5
Guideline :	Medical Device Regulation (EU) 2017/745
Conformity assessment route :	Class I: EU conformity declaration according to Article 52 (7) (EU) 2017/745, annex II + annex III.

Standards used :

EN-ISO-14971:2019+A11:2021	Medical devices - Application of risk management to medical devices.
EN-ISO-10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents.
EN-ISO-15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.
EN-ISO-20417:2021	Medical devices - Information to be supplied by the manufacturer.
EN-ISO-13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes.
Notified Body :	Not applicable (Medical Device Class I)

This declaration of conformity is issued under the sole responsibility of GOUKA BV. We hereby declare that the medical device(s) specified above meet the provision of the Medical Device Regulation (EU)2017/745.

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

Place, date : Den Haag, 15-6-2026

Signature :