EU Declaration of Conformity

Doc. No : MDR-DC-035

Rev. No : 2

Manufacturer :

DiaDent Group International

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Notified Body	:	TÜV Rheinland LGA Products GmbH			
Certificate	:	EN ISO 13485:2016	**Certificate No.**	:	SX_2020210-1
Issue date	:	2024-05-29	**Expiry date**	:	2027-06-01

Medical Device

Type of device	:	ENDODONTIC INSTRUMENTS
Product Name	:	**DIA-GP GAUGE**
Model Name	:	DIA-GP GAUGE , ENDOSTAR ENDOCALIBRATOR
Basic UDI -DI	:	88063835GPG4K
GMDN	:	64813

Classification

Class I (Rule 1) according to Annex VIII of the Medical Devices Regulation 2017/745

Conformity Assessment

to which this declaration relates,
meet(s) all the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices which apply to it and be carried out according to the Quality Management System EN ISO 13485:2016.

EU Declaration of Conformity is issued under the sole responsibility of DiaDent Group International.

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Quality Management Representative

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