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Regulatory Documentation	Declaration of Conformity – X-Smart Go Accessories	Rev. 02
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DECLARATION OF CONFORMITY
Medical devices

1. Manufacturer Information

Name:	Forum Engineering Technologies (96) Ltd.
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SPR:	Single registration number (SRN)- IL-MF-000023254

2. European Authorized Representative

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3. Declaration Statement

We, Forum Engineering Technologies (96) Ltd., Trademark-"Forumtec", hereby declares under its sole responsibility that the medical devices listed below, meet the provisions of the Regulation (EU) 2017/745 which apply to them, supported by the technical documentation prepared in accordance with to the Annex II and Annex III and in conformity with Article 19 and Annex IV of MDR 2017/74.

The intended purpose of these accessories is: To enable the proper functioning of the X-Smart Go cordless endo motor for canal enlargement and apex localization during root canal treatment.

Since accessories for a medical device shall be classified in their own right separately from the device with which they are used, the following accessories are all **non-invasive accessories** intended to enable a medical device to function according to its intended purpose and therefore are classified as **Class I** as per MDR Annex VIII-Chapter II (3.2), Rule 1:

- Measurement Cable
- File Clip
- Lip Clip
- Charging Power Bank (Cradle)
- Contra Angle
- Protective Silicone Sleeve

This declaration is based on MDR 2017/745 Annex VIII (Classification Rules) and the general safety and performance requirements set out in Annex I.

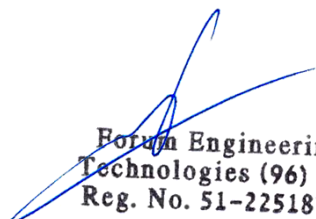
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This Declaration of Conformity covers the products specified in the Product List attached.

Product name	Product code	Model/Variant designation on device label	Basic UDI-DI (GS1)
X-Smart® Go Measurement cable	B00XSGOAC0001	X-Smart Go	++D100B00XSGOAC0001MT
X-Smart® Go File clip	B00XSGOAC0002	X-Smart Go	++D100B00XSGOAC0002MV
X-Smart® Go Lip clip	B00XSGOAC0003	X-Smart Go	++D100B00XSGOAC0003MX
X-Smart® Go Charger	B00XSGOAC0004	X-Smart Go	++D100B00XSGOAC0004MZ
X-Smart® Go Power bank	BSPXSGOAC0005	X-Smart Go	++D100BSPXSGOAC0005TL
X-Smart® Go Contra-angle 6:1	B00XSGOAC0006	X-Smart Go	++D100B00XSGOAC0006N5
X-Smart® Go Protective silicone sleeve	B00XSGOAC0007	X-Smart Go	++D100B00XSGOAC0007N7
X-Smart® Go Power Bank (Refurbished)	BRFXSGOAC0005	X-Smart Go	++D100BRFXSGOAC0005GR
X-Smart® Go Contra-angle (Refurbished)	BRFXSGOAC0006	X-Smart Go	++D100BRFXSGOAC0006GT

Note: The X-Smart Go Charger (B00XSGOAC0004) is a non-medical, off-the-shelf, CE-marked accessory and therefore does not require classification as a medical device accessory.

System Integration Note: These Class I accessories are specifically designed and validated to function with the cordless endo motor with integrated apex locator (Class IIa device covered under Document Reference: 5-EM7-000.DC). The complete system functionality and safety have been evaluated as an integrated unit during the technical documentation assessment of the main device.


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Technologies (96) Ltd
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Mark Averbuch- CEO

09.03.2026

Date

40 Hutsot Hayotser St., Ashkelon,
Israel

Place