DECLARATION OF CONFORMITY

Medical devices

1. Manufacturer Information

Name:	Forum Engineering Technologies (96) Ltd.
Tradename:	Forumtec
Address:	40 Hutsot Hayotser St., Ashkelon 7878563, Israel. P. O. Box 3095
Contact Details:	Tel.: +972-8-6788217 Fax.: +972-8-6788218, E-mail: info@forumtec.net
SPR:	Single registration number (SRN)- IL-MF-000023254

2. Notified Body

MDC medical device certification GmbH.
Kriegerstraße 6, 70191 Stuttgart, Germany
EC Notified Body Identification Number: 0483

3. European Authorized Representative

AR Experts BV
Boeingavenue 209
1119 PD Schiphol-Rijk
The Netherlands
info@ar-experts.eu
Single Registration Number (SRN): NL-AR-000023989

4. Declaration Statement

We, Forum Engineering Technologies (96) Ltd., Trademark- “Forumtec”, hereby declare that this declaration is issued under the sole responsibility of us as the manufacturer, and that the distributed CE marked product, specified below, is covered by the "CE Marking of Conformity Certificate. This declaration was issued under the Medical Device Regulation (MDR) 2017/745 on 04/06/2025, reference number: P25-00360-328078.

The intended purpose of the and its associated accessories device is: To assist dental professionals in performing canal enlargement and or apex localization and working length determination during root canal treatment.

The device is classified as Class IIa since it watches scope of Rule 9 which specifies “Active devices intended to administer or exchange energy are classified as Class IIa” (MDR Annex VIII -chapter III, Rule 9).

The embedded software is also classified as Class IIa since it watches the scope of Rule 11 which specifies "Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa" (MDR Annex VIII-Chapter III, Rule 11).

This declaration is based on MDR 2017/745 Annex IX, chapters I and III for the assessment of the QMS, and chapter II for the assessment of the technical documentation.

This declaration is supported by Quality System certification based on the harmonized standard EN ISO 13485:2016, registration number: P24-00415-294701, accredited by mdc medical device certification GmbH.

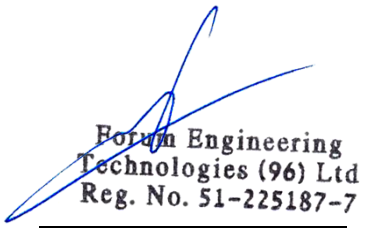
This Declaration of Conformity covers the product concerned, bearing CE marking and the associated accessories, manufactured by Forumtec, that comply with the following required applicable standards.

- 60601-1- "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- 60601-1-2 -"General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"

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)	Time related information (From SN.)
X-Smart® Go Cordless endo motor with integrated apex locator	B00XSGO000000	X-Smart Go	++D100B00XSGO00000093	EMGA000001
X-Smart Go Cordless endo motor with integrated apex locator (Refurbished)	BRFXSGO000000	X-Smart Go	++D100BRFXSGO0000003R	EMZA000001
X-Smart Go Handpiece	BSPXSGOAC0010	X-Smart Go	++D100BSPXSGOAC0010TD	EMGA000001
X-Smart Go Handpiece (Refurbished)	BRFXSGOAC0010	X-Smart Go	++D100BRFXSGOAC0010GJ	EMZA000001

Note: This device is designed to function with specific Class I accessories. For the complete list of compatible accessories and their conformity declaration, refer to the separate Declaration of Conformity for Class I Medical Device Accessories (Document Reference: 5-EM7-AC1.DC).



Mark Averbuch- CEO	09.03.2026	40 Hutsot Hayotser St., Ashkelon, Israel
Mark Averbuch- CEO	**Date**	**Place**