

EC Declaration of Conformity

according to the Regulation (EU) 2017/745

of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Class I Medical Device
(non-sterile, without measuring function)

Manufacturers Name:	Sanctuary Health Sdn Bhd
Manufacturers Address:	No 16, Persiaran Perindustrian Kanthan 1, Kawasan Perindustrian Kanthan, 31200 Chemor, Perak, Malaysia.
Manufacturer's SRN (Single Registration Number):	MY-MF-000002197
Authorized Representative Name (if applicable):	Wellkang Ltd (www.CE-marking.eu)
Authorized Representative Address (if applicable):	Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland.
Authorized Representative's SRN (Single Registration Number):	XI-AR-000001836
Basic UDI-DI:	955551401CCRS01K5
Name of the Device (s):	Sanctuary™ ComfiTract Latex-Free Cheek Retractor
Product code:	Refer to Attachment 1
Classification:	Class 1 (Non-Sterile, Without Measuring Function)
Rule:	5

Sanctuary Health Sdn. Bhd.

Reg No: 200201016304 (S63987-K)

Sanct Health Marketing Sdn. Bhd.

Reg No: 201501009101 (1134436-M)

Office

6B, (2nd Floor), Persiaran Greentown 4,
Greentown Avenue,
30450 Ipoh, Perak, Malaysia.
Tel No: +605 - 255 3939 | Fax No: +605 - 255 9339

Factory

No.16, Persiaran Perindustrian Kanthan 1,
Kawasan Perindustrian Kanthan,
31200 Chemor, Perak, Malaysia.
Tel No: +605 - 201 2800 | Fax No: +605 - 201 7800

Notified Body name: N/A

Notified Body Address: N/A

Notified Body Identification number: N/A

Intended Use: Used as a barrier during endodontic procedures.

Conformity assessment route: SANCTUARY HEALTH SDN. BHD. uses the following procedures for the CE-labeling of the products according the Regulation MDR 2017/745:

Class 1: EC conformity declaration according to Annex IV + Annex II and III Technical Documentation

This declaration of conformity is issued under the sole responsibility of SANCTUARY HEALTH SDN. BHD. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by BSI.

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

This declaration of conformity is valid for 5 years from the issued date.

Signature:



CHEE POI LENG
QAQC cum RA Manager

Place and date of issue:



Sanctuary Health, Chemor, Malaysia.
15 Dec 2025

Attachment 1

Product Code	UDI-DI (GTIN)		Description
	Inner Box	Outer Carton	
CR001-S63-P319	09555514016012	19555514016019	Sanctuary™ ComfiTract Latex Free Cheek Retractor 85mm (Large) (Box)
CR002-S63-P319	09555514016029	19555514016026	Sanctuary™ ComfiTract Latex Free Cheek Retractor 75mm (Medium) (Box)
CR001-S63-P320	09555514016685	09555514016682	Sanctuary™ ComfiTract Latex Free Cheek Retractor 85mm (Large) (Pc)
CR002-S63-P320	09555514016692	09555514016699	Sanctuary™ ComfiTract Latex Free Cheek Retractor 75mm (Medium) (Pc)

Sanctuary Health Sdn. Bhd.

Reg No: 200201016304 (583967-IQ)

Sanct Health Marketing Sdn. Bhd.

Reg No: 201501009101 (1134436-M)

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