

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:	955551400LDDSH01JW
Name of the Device (s):	Sanctuary™ Latex Dental Dam
Product code:	Refer to Attachment 1
Classification:	Class 1 (Non-Sterile, Without Measuring Function)
Rule:	5
Notified Body name:	N/A
Notified Body Address:	N/A

SH-QA-016-01

Sanctuary Health Sdn. Bhd. Reg No: 200201016304 (583967-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

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Page 1 of 4



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 to 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 DQS.

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.
19 JAN 2023

SH-QA-016-01

Page 2 of 4

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Attachment 1

Product Code	GTIN	Description
DL512B-ECSH0	09555514007553	Sanctuary™ 5"X5" Latex Dental Dam-Blue, Thin (for colour box)
DL512B-ECSH0	19555514007550	Sanctuary™ 5"X5" Latex Dental Dam-Blue, Thin (for carton)
DL522B-ECSH0	09555514007560	Sanctuary™ 5"X5" Latex Dental Dam-Blue, Medium (for colour box)
DL522B-ECSH0	19555514007567	Sanctuary™ 5"X5" Latex Dental Dam-Blue, Medium (for carton)
DL532B-ECSH0	09555514007577	Sanctuary™ 5"X5" Latex Dental Dam-Blue, Heavy (for colour box)
DL532B-ECSH0	19555514007574	Sanctuary™ 5"X5" Latex Dental Dam-Blue, Heavy (for carton)
DL612B-EBSH0	09555514007652	Sanctuary™ 6"X6" Latex Dental Dam-Blue, Thin (for colour box)
DL612B-EBSH0	19555514007659	Sanctuary™ 6"X6" Latex Dental Dam-Blue, Thin (for carton)
DL622B-EBSH0	09555514007669	Sanctuary™ 6"X6" Latex Dental Dam-Blue, Medium (for colour box)
DL622B-EBSH0	19555514007666	Sanctuary™ 6"X6" Latex Dental Dam-Blue, Medium (for carton)
DL632B-EBSH0	09555514007676	Sanctuary™ 6"X6" Latex Dental Dam-Blue, Heavy (for colour box)
DL632B-EBSH0	19555514007673	Sanctuary™ 6"X6" Latex Dental Dam-Blue, Heavy (for carton)
DL511A-ECSH0	09555514008550	Sanctuary™ 5"X5" Latex Dental Dam-Green, Thin (for colour box)
DL511A-ECSH0	19555514008557	Sanctuary™ 5"X5" Latex Dental Dam-Green, Thin (for carton)
DL521A-ECSH0	09555514008567	Sanctuary™ 5"X5" Latex Dental Dam-Green, Medium (for colour box)
DL521A-ECSH0	19555514008564	Sanctuary™ 5"X5" Latex Dental Dam-Green, Medium (for carton)
DL531A-ECSH0	09555514008574	Sanctuary™ 5"X5" Latex Dental Dam-Green, Heavy (for colour box)
DL531A-ECSH0	19555514008571	Sanctuary™ 5"X5" Latex Dental Dam-Green, Heavy (for carton)
DL611A-EBSH0	09555514008659	Sanctuary™ 6"X6" Latex Dental Dam-Green, Thin (for colour box)
DL611A-EBSH0	19555514008656	Sanctuary™ 6"X6" Latex Dental Dam-Green, Thin (for carton)
DL621A-EBSH0	09555514008666	Sanctuary™ 6"X6" Latex Dental Dam-Green, Medium (for colour box)
DL621A-EBSH0	19555514008663	Sanctuary™ 6"X6" Latex Dental Dam-Green, Medium (for carton)
DL631A-EBSH0	09555514008673	Sanctuary™ 6"X6" Latex Dental Dam-Green, Heavy (for colour box)
DL631A-EBSH0	19555514008670	Sanctuary™ 6"X6" Latex Dental Dam-Green, Heavy (for carton)
DL571H-ECSH0	09555514008864	Sanctuary™ 5"X5" Latex Dental Dam-Black, Thin (for colour box)
DL571H-ECSH0	19555514008861	Sanctuary™ 5"X5" Latex Dental Dam-Black, Thin (for carton)
DL561H-ECSH0	09555514008857	Sanctuary™ 5"X5" Latex Dental Dam-Black, Medium (for colour box)
DL561H-ECSH0	19555514008854	Sanctuary™ 5"X5" Latex Dental Dam-Black, Medium (for carton)
DL581H-ECSH0	09555514008871	Sanctuary™ 5"X5" Latex Dental Dam-Black, Heavy (for colour box)
DL581H-ECSH0	19555514008878	Sanctuary™ 5"X5" Latex Dental Dam-Black, Heavy (for carton)
DL671H-EBSH0	09555514008833	Sanctuary™ 6"X6" Latex Dental Dam-Black, Thin (for colour box)
DL671H-EBSH0	19555514008830	Sanctuary™ 6"X6" Latex Dental Dam-Black, Thin (for carton)
DL661H-EBSH0	09555514008826	Sanctuary™ 6"X6" Latex Dental Dam-Black, Medium (for colour box)
DL661H-EBSH0	19555514008823	Sanctuary™ 6"X6" Latex Dental Dam-Black, Medium (for carton)
DL681H-EBSH0	09555514008840	Sanctuary™ 6"X6" Latex Dental Dam-Black, Heavy (for colour box)
DL681H-EBSH0	19555514008847	Sanctuary™ 6"X6" Latex Dental Dam-Black, Heavy (for carton)
DL533L-ECSH0	09555514007690	Sanctuary™ 5"X5" Latex Dental Dam-Silk Blue, Thin (for colour box)
DL533L-ECSH0	19555514007697	Sanctuary™ 5"X5" Latex Dental Dam-Silk Blue, Thin (for carton)

SH-QA-016-01

Page 3 of 4

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DL593L-EBSH0	09555514007706	Sanctuary™ 5"X5" Latex Dental Dam-Silk Blue, Medium (for colour box)
DL593L-EBSH0	19555514007703	Sanctuary™ 5"X5" Latex Dental Dam-Silk Blue, Medium (for carton)
DL633L-EBSH0	09555514007713	Sanctuary™ 6"X6" Latex Dental Dam-Silk Blue, Thin (for colour box)
DL633L-EBSH0	19555514007710	Sanctuary™ 6"X6" Latex Dental Dam-Silk Blue, Thin (for carton)
DL693L-EBSH0	09555514007720	Sanctuary™ 6"X6" Latex Dental Dam-Silk Blue, Medium (for colour box)
DL693L-EBSH0	19555514007727	Sanctuary™ 6"X6" Latex Dental Dam-Silk Blue, Medium (for carton)
DL573S-ECSH0	09555514007782	Sanctuary™ 5"X5" Latex Dental Dam-Pink, Thin (for colour box)
DL573S-ECSH0	19555514007789	Sanctuary™ 5"X5" Latex Dental Dam-Pink, Thin (for carton)
DL563S-ECSH0	09555514007775	Sanctuary™ 5"X5" Latex Dental Dam-Pink, Medium (for colour box)
DL563S-ECSH0	19555514007772	Sanctuary™ 5"X5" Latex Dental Dam-Pink, Medium (for carton)
DL583S-ECSH0	09555514007799	Sanctuary™ 5"X5" Latex Dental Dam-Pink, Heavy (for colour box)
DL583S-ECSH0	19555514007796	Sanctuary™ 5"X5" Latex Dental Dam-Pink, Heavy (for carton)
DL673S-EBSH0	09555514007751	Sanctuary™ 6"X6" Latex Dental Dam-Pink, Thin (for colour box)
DL673S-EBSH0	19555514007758	Sanctuary™ 6"X6" Latex Dental Dam-Pink, Thin (for carton)
DL663S-EBSH0	09555514007744	Sanctuary™ 6"X6" Latex Dental Dam-Pink, Medium (for colour box)
DL663S-EBSH0	19555514007741	Sanctuary™ 6"X6" Latex Dental Dam-Pink, Medium (for carton)
DL683S-EBSH0	09555514007768	Sanctuary™ 6"X6" Latex Dental Dam-Pink, Heavy (for colour box)
DL683S-EBSH0	19555514007765	Sanctuary™ 6"X6" Latex Dental Dam-Pink, Heavy (for carton)
DL565S-ECSH0	09555514009540	Sanctuary™ 5"x5" Latex Dental Dam-Pink, Medium (for colour box)
DL565S-ECSH0	19555514009547	Sanctuary™ 5"x5" Latex Dental Dam-Pink, Medium (for carton)
DL665S-EBSH0	09555514009564	Sanctuary™ 6"x6" Latex Dental Dam-Pink, Medium (for colour box)
DL665S-EBSH0	19555514009561	Sanctuary™ 6"x6" Latex Dental Dam-Pink, Medium (for carton)

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Page 4 of 4

