DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer: CDM Center of Excellence Ltd.

Address: Golden Land Building Office 1302A,Liangmaqiao Road No.32,Chaoyang District, 100125 Beijing China

EC Representative:

StateLab GmbH

Friedrich-Ebert-Straße 7

58642 Iserlohn

DIMDI Code:DE/0000049337

Product Name:

The Natural Latex Dental Dam (Endostar EASY dam)

Model: Thin, Medium , Heavy,

Size: 5 X5" 6X6"

Classification：Class I

Rule：Rule 1, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971:2012 EN ISO 15223-1:2016

EN 1041:2008+A1:2013 ISO 10993-1:2018

EN ISO 10993-5:2009 EN ISO 10993-10:2013

Signature:

Name/ Position: Dr. Bruno Grassegger / General Manager

Date: 2021/03/10

Place: Beijing/ China