

EU Declaration of Conformity

Manufacturer's Name: Shenzhen Dongdixin Technology Co., Ltd.

Manufacturer's Address: Floor 1-2, No.3 Building, Fanshen Xusheng Industrial Estate
Xilixiaobaimang, Nanshan District, 518108 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA

Manufacturer's SRN: CN-MF-000009429

Authorized Representative's Name: Shanghai international holding Corp. GmbH (Europe)

Authorized Representative's Address: Eiffestraße 80, 20537 Hamburg Germany

Authorized Representative's SRN: DE-AR-000000001

Basic UDI-DI: 69264087CH001HT

Name of the Device: Bite Gone

Model: CH3000 Type: Pro

Hartmann Item Number: 9256112/9256121

Classification: Class IIa, Rule 9 according to Annex VIII of the MDR 2017/745

EMDN Code: V9099, VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES –
OTHER

Notified Body name: SGS FIMKO OY

Notified Body's Address: Takomotie 8
FI-00380 HELSINKI
Finland

Notified Body Identification number: 0598

Certificate No FI23/0000008
Issue date 2023-03-21
Expiry date 2029-03-20

Conformity assessment route: Shenzhen Dongdixin Technology Co., Ltd. uses the following
procedures for the CE-labeling of their products according to
Regulation MDR 2017/745:

Class IIa: EC conformity declaration according to annex IX exclude
chapter II

This declaration of conformity is issued under the sole responsibility of Shenzhen Dongdixin Technology Co., Ltd. We hereby declare that the medical device specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

Additionally, the device is in conformity with the following Union legislation:

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and its amendments.

Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and its amendments.

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

Shenzhen, 2026-03-26

Place, date



Siping Yuan, R.A. Director

Legally binding signature, Function