



EU Declaration of Conformity

The following description for the medical device,

Common Device name: **Tongue Depressors**

Single Registration Number (SRN): **TW-MF-000012009**

Basic UDI-DI: 4719884082021VTR00009L

UMDNS code: 14066, Tongue Depressors

GMDN code: 42461, Tongue Depressor, Examination

Common Specification (CS) references: Wooden Tongue Depressors

Risk class of the device: **Class I**

Is covered by the present declaration is conformity with the Medical Device Regulation 2017/745/EU as amended by 2020/561/EU.

For the evaluation regarding Class I device, the following harmonized standards are applied:

EN ISO 10993-1: 2020, EN ISO 13485: 2016, ISO 14971:2019

EN ISO 15223-1:2021, EN62366-1: 2015

The following European Union authorized representation is stated to the declaration:

Y. Sung Handelsvertretung

Duesselthaler Str. 24, 40211 Duesseldorf Germany

(Company name / Registered place of business)

The following person is exclusively responsible for the compliance of declaration:

Hsin Mawh Enterprise Co., Ltd.

No. 1465, Sec. 3, Chi San Road, Chu San Chen, Nantou Hsien, 55762, Taiwan

(Manufacturer's name / Registered address)

Wu, Chun-Te / General Manager

(Name / Function)

(Legal Signature)

October 15, 2021

(Date of Issue)

Issued date: October 15, 2021

Version: V1.0