

## EU Declaration of Conformity

Manufacturer: Goodwood Medical Care Ltd

Whose single Authorized Representative:

CMC Medical Devices & Drugs S.L.

Address: 1-2 Floor, 3-919, Yongzheng Street, Jinzhou District, Dalian Liaoning, China

Address: C/ Horacio Lengo No18, CP 29006, Málaga, Spain

WE, AS THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

HEREWITH DECLARE THAT /

the STATE medical device:/

Tongue Depressors

Model:/

GW-1102/GW-1106/GW-/1108/GW-1110

GMDN Code:/

14066

Basic UDI:\_

697312826GW010DT

Of class:/

I, RULE 5(5.1/1) according to Annex VIII of Regulation EU 2017/745(MDR)

meets the provisions of Regulation EU 2017/745(MDR) and its transportations in national laws which apply to it.

The declaration is valid in connection with the "final inspection report" of the device. /

Applicable harmonized standards are: /

EN ISO13485:2016/EN ISO14971:2019/EN 62366-1:2015/EN 1041: 2008+A1:2013/EN ISO 15223-1:2016/ISO 10993-1:2018/EN ISO10993-5:2009/EN ISO 10993-10:2013

Dalian, 2021-05-20

CEO



Ort, Datum / Place, date /

Lieu, date / Luogo, data

Name und Funktion / Name and function /

Nom et fonction / Nome e funzione