

Technical File of Tongue Depressors

EU Declaration of Conformity

Manufacturer: Goodwood Medical Care Ltd	Whose single Authorized Representative: CMC Medical Devices & Drugs S.L.
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District, Dalian Liaoning, China	Spain

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

HEREWITH DECLARE HIAT	
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

Ort, Datum / Place, date / Lieu, date / Luogo, data

CEO Name und unktion / Na .e an. function / Nom et fonc. 2017 Nome e funzione