



GUANGDONG GENIAL TECHNOLOGY CO., LTD.

DECLARATION OF CONFORMITY

Manufacturing Name: *Guangdong GENIAL TECHNOLOGY CO., LTD.*

Name and address of the firm

Company Address: *I-6-05-02, 11th Road, Area B, Guangfozhao Economic Cooperation Zone, Zhagang Town, Huaiji County, Zhaoqing City, Guangdong, 526437, China*

Authorized European Representative:

Company name: *MedPath GmbH*

Address: *Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany*

We, the manufacturer, declare under our sole responsibility that

the medical device

Product Name: *Digital Thermometer (T Series)*

Including *DT-15 (T15S)*

Name, type or model, batch or serial number, possibly sources and number of items

of class

Class II a Rule 10

according to annex IX of direct. 93/42/EEC As amended by 2007/47/EC

meets all the provisions of the directive 93/42/EEC As amended by 2007/47/EC which apply to it.

Applied harmonised standards, national standards or other normative documents

EN/ISO14971:2012	EN15223-1:2012
EN 1041:2008	EN 60601-1:2006/A1 :2013
EN 60601-1-2:2015	EN 60601-1-6:2010
EN 60601-1-8:2007/AC :2010	EN-60601-1-11:2015
EN/ISO 10993-1:2009/AC:2010	EN/ISO 10993-5:2009
EN/ISO 10993-10:2013	EN/ ISO 80601-2-56:2017
IEC 62304-1:2006/AC:2008	EN14155
MEDDEV 2.7/1 revision 4	
MEDDV2.12/1 rev 8	MEDDV2.12.2
MDD Annex VII + Annex V	

Conformity assessment procedure

Notified Body (if consulted):
SGS Belgium NV, Notified Body
Country: Belgium
SGS House Noorderlaan 87 2030 Antwerp Belgium
email : admin@genial.cn

CE1639

Certificate number

CN19/41108

Zhaoqing, Guangzhou, China, 23rd October, 2024

Position: general manager

Place, date

Name and function