

Declaration Of Conformity



MANUFACTURER:

MICOMME MEDICAL TECHNOLOGY DEVELOPMENT CO., LTD.
SUPERSTAR ENTERPRISE CENTER
No 8, LUJING ROAD
HIGH-TECH ZONE
410205 CHANGSHA, HUNAN
PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE:

Sleep Apnoea Therapy Devices
MODEL:
CPAP A20; CPAP 25; CPAP A25; BPAP 30; BPAP A30;
BPAP 30lite; ST-30D; ST-30E; ST-30F; C1; C2; C3; C5;
B1; B5; S1; T1; T2; T3; T5; P1; ST-30A; ST-30C.

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE11

CONFORMITY ASSESSMENT ROUTE: ANNEX II. (EXCLUDE II.4)

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE
93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DoC

NOTIFIED BODY:

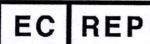
TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

0123

(EC) CERTIFICATE(S):

No.G1 093291 0001 REV.03



EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH
(Europe)
EIFFESTRASSE 80, D-20537 HAMBURG, GERMANY

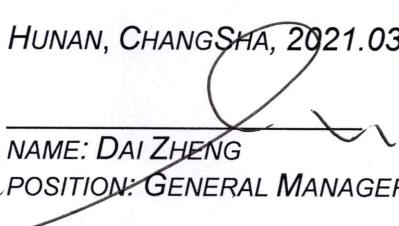
START OF CE-MARKING:

2016.02.19

PLACE, DATE OF DECLARATION:

HUNAN, CHANGSHA, 2021.03.15

SIGNATURE:


NAME: DAI ZHENG
POSITION: GENERAL MANAGER