

Declaration of Conformity

to Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices

MANUFACTURER:

Qinhuangdao Kapunuomaite Medical Equipment S&T Co., Ltd.

MEDICAL DEVICE: EtCO₂ Sensor

MODEL: CMZ60MEMO

GMDN CODE: 36552

CLASSIFICATION - ANNEX IX: CLASS IIb, RULE10

CONFORMITY ASSESSMENT ROUTE: MDD ANNEX II WITHOUT 4

WE, QINHUANGDAO KAPUNUOMAITE MEDICAL EQUIPMENT S&T CO., LTD. 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.

A STATEMENT THAT MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC .

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

ISO 14971:2012	IEC 60601-1:2006+A1:2013	IEC 60601-1-2:2014
IEC 60601-1-8:2007+A1: 2013	ISO 80601-2-55:2018	IEC 62366-1:2015
ISO 15223-1:2016	EN 1041:2008	

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

IDENTIFICATION NUMBER 123

(EC) CERTIFICATE(S): G1 103623 0002 Rev.00

SHOW ONLY THE EC CERTS WITH A SCOPE THAT COVERS THE PRODUCTS LISTED

EC REP

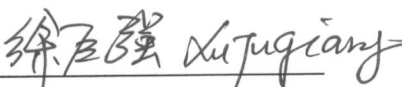
EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80,20537 Hamburg,Germany

START OF CE-MARKING: 2019-11-13

USUALLY = ISSUE DATE OF EC CERT. (AND ADD END DATE - WHEN EC CERT. VALIDITY ENDS,
OR WHEN DEVICE CEASES TO BE MARKETED, OR WHEN NB IS CHANGED)

PLACE, DATE OF DECLARATION: QINHUANGDAO, HEBEI PROVINCE. 2021-5-20

SIGNATURE:


NAME: XUJUQIANG
POSITION: GM