

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES**



MANUFACTURER:
ADDRESS:

SHENZHEN EVERBEST MACHINERY INDUSTRY CO., LTD.
19TH BUILDING, 5TH REGION, BAIWANGXIN INDUSTRIAL PARK,
SONGBAI RD, BAIMANG, XILI, NANSHAN, SHENZHEN,
GUANGDONG 518108, CHINA

MEDICAL DEVICE:

NON-CONTACT FOREHEAD INFRARED THERMOMETER: DT-8807S, DT-8807H

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 10

CONFORMITY ASSESSMENT ROUTE:

ANNEX II WITHOUT (4)

WE, SHENZHEN EVERBEST MACHINERY INDUSTRY CO., LTD., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
WE, THE MANUFACTURER, ARE EXCLUSIVELY RESPONSIBLE FOR THE DOC.

STANDARDS APPLIED:

SEE TF-05 APPLIED STANDARD LIST

NOTIFIED BODY:

TÜV RHEINLAND GROUP

IDENTIFICATION NUMBER

CE 0197

(EC) CERTIFICATE(S):

DD 60139343 0001

**APPLIED HARMONISED STANDARDS
NATIONAL STANDARDS OR
OTHER NORMATIVE DOCUMENTS:**

IEC 60601-1:2005+A1:2012
EN 60601-1:2006+A11:2011+A1:2013+A12:2014
IEC 60601-1-2:2014 EN 60601-1-2:2015
IEC 60601-1-11:2015 EN 60601-1-11:2015
ISO 80601-2-56:2017+A1:2018

VALID UNTIL:

2024-5-24



EUROPEAN REPRESENTATIVE:

LOTUS NL B.V.
KONINGIN JULIANAPLEIN 10, 1E VERD, 2595AA, THE
HAGUE, NETHERLANDS

PLACE, DATE OF DECLARATION:

SHENZHEN, GUANGDONG, 2020-05-13

SIGNATURE:


NAME: YUAN JIANMIN
POSITION: GENERAL MANAGER