

Certificate of Compliance



No. OP150728.FHSDN25

Certificate's
Holder:

FUWEI HIGH SCIENTIFIC CO.,LTD.
No. 77 Lane 311, Nangong St., Yonukang City,
Taiwan County 710, Taiwan (R.O.C.)

Manufacturer:

Ahead Electrical Co., Ltd.
No. 6-56, Nanjin Rd., Wanluan Township, Pingtung
County 92341, Taiwan (R.O.C.)

Certification ECM
Mark:



Product:

High-Voltage Electric Field Therapy
-SAKAE-380ma

Model(s):

SAKAE-380ma

Verification to:

Standard:
EN1041:2008, EN ISO 10993-1:2009+AC:2010,
EN ISO 10993-5:2009, EN ISO 10993-10:2013,
EN ISO 15223-1:2012,
EN 60601-1:2006+A1:2013,
EN ISO 14971:2012

related to CE Directive(s):
93/42/EEC (Medical Devices Directive) including
2007/47/EC (Medical Devices)

Remark: The product(s) has been verified on a voluntary basis. The product(s) satisfies the requirements of the Certification Mark of ECM, in reference to the above listed Standard(s). The above Certification Mark can be affixed on the product(s) accordingly to the ECM regulation about its release and its use. Regulation can be found at www.entecerma.it.

Whereas the Manufacturer is responsible of the CE certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.

The Manufacturer is also responsible to maintain efficient the internal production control to ensure the product(s) are in compliance with the Certification Mark.

This certificate can be checked for validity at www.entecerma.it

Date of issue 28 July 2015

Expiry date 27 July 2020

Chief Manager
Tim Mahan



Deputy Manager
Viola Miller



Ente Certificazione Macchine Srl

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