

Verification of Compliance



No. EC.1282.0A140311.WHH0789

Certificate's Holder: ZENITH LAB(JIANGSU)CO.,LTD

No.12,Hongshan Road,Jincheng Industrial Area,
Jintan, Jiangsu, China

Product: STEAM STERILIZERS

Model(s): LDZX-40(50 75 100 150)B(BD)(BP)
DGL-30(35 40 50 60 75 80 100)A(B G1 G2)
DGS-280(A B C A+ B+ C+)B8C,B12C,B16V
B18C,B23C,B8C-V,B18C-V,B23C-V,B45C-V

Directives: 93/42/EEC Medical devices

Standards: EN 13060:2014 EN 61010-1:2010
EN 60601-1-2:2015 EN ISO 14971:2012

Remark: This Verification of Compliance has been issued on a voluntary basis. ECM confirms that a Technical Construction File (TCF) is existent for the above listed product(s). The TCF satisfactorily covers the essential requirements of the above listed Directive(s).

Other relevant Directives have to be observed in case they are applicable.

This Document is only valid for the equipment and configuration described and in conjunction with the TCF detailed above. Whereas the Manufacturer is responsible of the 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 of the internal production control to ensure the product(s) are in compliance with the essential requirements of the above mentioned Directive(s).

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

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Expiry date MARCH 2024

Certification Chief Manager

Tim Mahan



Certification Deputy Manager

Viola Müller

