

## TWD TradeWinds, Inc. LakeView Corporate Park 10555 86<sup>th</sup> Ave. Pleasant Prairie, WI 53158 USA

Date	04/15/2009	From	TWD TradeWinds Inc
Product	Certificate of Sterilization	Phone	262-605-3263
Ref. #	Item # DF8088S Forceps	Fax	262- 605-3262
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## **Certificate of Sterilization**

The validation and routine control of the sterilization procedure are carried out in accordance with the following standards.

EN 550: Sterilization of medical devices –

Validation and routine control for Ethylene Oxide Sterilization.

EN 556: Sterilization of medical devices –

Requirements for medical devises to be labeled "sterile."

Provided appropriate storage products remain sterile for at least 5 years from sterilization date. The bio monitors for the sterilization in accordance with EN550 and EN556 have shown no bacteria growth. The sterilization of enclosed listed products has been approved.

Sterilization Manager, Alan Happel

## **Certificate of Conformance**

We hereby certify that below mentioned products meet the specifications stated.

Product type: Forceps Blue

Product Specification: 84011462

Lot no.: 612635

Lot quantity: 301.200 pcs.

Invoice no.: 1121677

All products are produced in accordance with the requirements of DS/ENISO 13485 and the Medical Device Directive 93/42/EEC (CE-mark approval).