



Convatec

CERTIFICATE OF STERILISATION

This is to certify that the item

84011182 Forceps blue Lot no. 643124, 643278, 643309, 643605,
643741, 643876, 644157

has been manufactured by Unomedical a/s, are sterilized by Ethylene Oxide.

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

EN ISO 11135-1: 2007 Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilizations process for medical devices

EN 556-1: 2008 Sterilization of medical devices – Requirements for medical devices to be designated “Sterile” – Part 1: Requirements for terminally sterilized medical devices

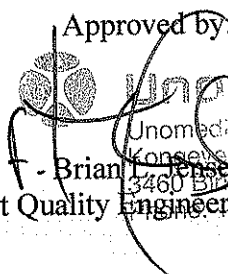
EN ISO 10993-7: 2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals

Routine control: The criteria for product release from sterilization
- Conformity with the specified physical parameters for the sterilization cycle
- No growth of the biological indicators

Provided appropriately stored, products remain sterile for at least 5 years from the sterilization date.

“We, Unomedical a/s, guarantee, that the amount of the EO residuals remaining in the products after the sterilization process, does not exceed the amount stipulated in the international standard

Approved by:


Unomedical
Unomedical a/s
Kongsgaard 2
13460 Bjerringø - Denmark
Product Quality Engineering Manager