

Quality System Certificate

Certificate No.:
DGM – 766

Reference:
aur5a1901v370f339

Date of issue:
2019-01-22

Valid Until:
2021-11-08

Initial date of issue:
2011-10-11

This is to certify that the quality system of:

Plum A/S
Frederik Plums Vej 2
5610 Assens
Denmark

fulfills the requirements in:

DS/EN ISO 13485:2016

The certificate covers the following activities:

Manufacture of wound rinse products, adhesive bandages and eye irrigation fluids for first aid.
Sale of cleansing pads, cooling gel and wound dressings for first aid and wipes for disinfection.

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001:2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S