

SAO Y BẢN CHÍNH
Ngày 24 tháng 7 năm 2019



EC Certificate

Certificate Number: DGM - 887

This is to certify that the quality system of:

Vitrex Medical A/S
Vasekær 6-8
2730 Herlev
Denmark



[Signature]
GIÁM ĐỐC
Vương Đức Tuấn

has been approved in conformity with the requirements of

Annex II Full quality assurance system

of Council Directive 93/42/EEC concerning medical devices as ammended and transposed into Danish law, excluding Annex II, section 4.

The certificate covers the following activities:

Design and Manufacturing of sterile blood lancets and sterile safety lancets in class IIa

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the Directive.

[Signature]
Heidi Jørgensen
Authorized person
For Presafe Denmark A/S

Date of issue: 2016-07-07
Expires: 2021-07-07
Initial date of issue: 2016-07-07
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Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

