EC Certificate

Certificate Number: DGM – 859

This is to certify that the quality system of:

Innovision ApS
Skovvænget 2
5620 Glamsbjerg
Denmark

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, manufacture and final inspection of cardiopulmonary function test equipment 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.

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue:	2015-07-06
Expires:	2020-07-06
Initial date of issue:	2015-07-06
Reference:	aur2a1503v301f282

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

Product List

The following products are covered by DGM – 859:

Product	Class	Date for placing on the market (with CE Mark)	Product family on DGM – 859 covering the device
INN00010	IIa	2008-02-23	Innocor
INN00050	IIa	Before 2005-08-15	Innocor
INN00100	IIa	Before 2005-08-15	Innocor
INN00400	IIa	2013-05-15	Innocor
INN00010-1	IIa	2016-11-15	Innocor
INN00050-1	IIa	2016-11-15	Innocor
INN00100-1	IIa	2016-11-15	Innocor
INN00400-1a	IIa	2016-11-15	Innocor
INN00400-1b	IIa	2016-11-15	Innocor
INN00400-1c	IIa	2016-11-15	Innocor

"The products on this list have been accepted by Presafe Denmark A/S"

Date: 2017-01-10

Name and signature: Carsten Worm Jensen

Title: Lead auditor

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