



EC Design Examination Certificate

Certificate Number: DGM – 780

This is to certify that the defined representative samples of the device manufactured by:

SP Medical A/S
Møllevej 1
4653 Karise
Denmark

have been approved in conformity with the requirements of

Annex II Section 4 - Examination of the design of the product

of Council Directive 93/42/EEC concerning medical devices as transposed into Danish law.

The certificate covers the following devices:

PTFE and stainless steel Guide Wires in class III

The Design Examination certificate is valid provided that no changes are made to the approved design that could affect conformity with the essential requirements or the conditions prescribed for use for the product without the approval of Presafe Denmark A/S. The EC-Design Examination certificate is issued in accordance with Presafe Denmark A/S' terms and conditions cf. Council Directive 93/42/EEC concerning medical devices as transposed into Danish law. The certificate is based on successful evaluation of the device design.


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2018-09-06
Expires: 2022-03-03
Initial date of issue: 2012-03-02
Reference: aur2a1809v260f766



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

DGM

The following products in class III are covered by the certificate:

Accoat Guide Wires

Seldinger Straight

REF Number	Date for first CE Mark
S-018-L	2012.03.02
S-021-L	2012.03.02
S-025-L	2012.03.02
S-028-L	2012.03.02
S-032-L	2012.03.02
S-035-L	2012.03.02
S-038-L	2012.03.02
S-C-018-L	2012.03.02
S-C-021-L	2012.03.02
S-C-025-L	2012.03.02
S-C-028-L	2012.03.02
S-C-032-L	2012.03.02
S-C-035-L	2012.03.02
S-C-038-L	2012.03.02
H-S-018-L	2012.03.02
H-S-021-L	2012.03.02
H-S-025-L	2012.03.02
H-S-028-L	2012.03.02
H-S-032-L	2012.03.02
H-S-035-L	2012.03.02
H-S-038-L	2012.03.02
H-S-C-018-L	2012.03.02
H-S-C-021-L	2012.03.02
H-S-C-025-L	2012.03.02
H-S-C-028-L	2012.03.02
H-S-C-032-L	2012.03.02
H-S-C-035-L	2012.03.02
H-S-C-038-L	2012.03.02
H-X-S-028-L	2012.03.02
H-X-S-032-L	2012.03.02
H-X-S-035-L	2012.03.02
H-X-S-038-L	2012.03.02
H-X-S-C-028-L	2012.03.02
H-X-S-C-032-L	2012.03.02

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Seldinger Straight

REF Number	Date for first CE Mark
H-X-S-C-035-L	2012.03.02
H-X-S-C-038-L	2012.03.02
H-X-X-S-028-L	2012.03.02
H-X-X-S-032-L	2012.03.02
H-X-X-S-035-L	2012.03.02
H-X-X-S-038-L	2012.03.02
H-X-X-S-C-028-L	2012.03.02
H-X-X-S-C-032-L	2012.03.02
H-X-X-S-C-035-L	2012.03.02
H-X-X-S-C-038-L	2012.03.02

Allowed Optional variants

A suffix **AAYY** can if needed be added at the end of the above listed REF numbers:
Purpose, handle national label requirements and identification of different distributors in specific countries

S (straight) is the shape of the tip
C is PTFE coated
H-X is extra stiff
L is a variable in the standard article number.

018-038 is the diameter in inches.
H is stiff
H-X-X is super stiff
L is the total length of the guide wire in the range from 10 cm. to 450 cm.

Optional suffix handling national requirements:

AA is country abbreviation written with 2 characters.

YY is a number from 01 to 99 in cases were REF number is to identify specific distributors in specific countries.

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Seldinger J-tip

REF Number	Date for first CE Mark
Jr-018-L	2012.03.02
Jr-021-L	2012.03.02
Jr-025-L	2012.03.02
Jr-028-L	2012.03.02
Jr-032-L	2012.03.02
Jr-035-L	2012.03.02
Jr-038-L	2012.03.02
Jr-C-018-L	2012.03.02
Jr-C-021-L	2012.03.02
Jr-C-025-L	2012.03.02
Jr-C-028-L	2012.03.02
Jr-C-032-L	2012.03.02
Jr-C-035-L	2012.03.02
Jr-C-038-L	2012.03.02
H-Jr-018-L	2012.03.02
H-Jr-021-L	2012.03.02
H-Jr-025-L	2012.03.02
H-Jr-028-L	2012.03.02
H-Jr-032-L	2012.03.02
H-Jr-035-L	2012.03.02
H-Jr-038-L	2012.03.02
H-Jr-C-018-L	2012.03.02
H-Jr-C-021-L	2012.03.02
H-Jr-C-025-L	2012.03.02
H-Jr-C-028-L	2012.03.02
H-Jr-C-032-L	2012.03.02
H-Jr-C-035-L	2012.03.02
H-Jr-C-038-L	2012.03.02
H-X-Jr-028-L	2012.03.02
H-X-Jr-032-L	2012.03.02
H-X-Jr-035-L	2012.03.02
H-X-Jr-038-L	2012.03.02
H-X-Jr-C-028-L	2012.03.02
H-X-Jr-C-032-L	2012.03.02
H-X-Jr-C-035-L	2012.03.02
H-X-Jr-C-038-L	2012.03.02
H-X-X-Jr-028-L	2012.03.02
H-X-X-Jr-032-L	2012.03.02
H-X-X-Jr-035-L	2012.03.02

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Seldinger J-tip

REF Number	Date for first CE Mark
H-X-X-Jr-038-L	2012.03.02
H-X-X-Jr-C-028-L	2012.03.02
H-X-X-Jr-C-032-L	2012.03.02
H-X-X-Jr-C-035-L	2012.03.02
H-X-X-Jr-C-038-L	2012.03.02

Allowed Optional variants

A suffix **AAYY** can if needed be added at the end of the above listed REF numbers:
Purpose, handle national label requirements and identification of different distributors in specific countries

Jr is the shape of the tip in mm (rad. 1,5-15mm)
C is PTFE coated
H-X is extra stiff
L and **r** are variables in the standard article number.
r is the radius of the J tip in the range from 1,5 mm. to 15 mm.

018-038 is the diameter in inches.
H is stiff
H-X-X is super stiff
L is the total length of the guide wire in the range from 10 cm. to 450 cm.

Optional suffix handling national requirements:

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Seldinger Double Ended

REF Number	Date for first CE Mark
D-S-Jr-025-L	2012.03.02
D-S-Jr-032-L	2012.03.02
D-S-Jr-035-L	2012.03.02
D-S-Jr-038-L	2012.03.02
D-S-Jr-C-025-L	2012.03.02
D-S-Jr-C-032-L	2012.03.02
D-S-Jr-C-035-L	2012.03.02
D-S-Jr-C-038-L	2012.03.02
H-D-S-Jr-025-L	2012.03.02
H-D-S-Jr-032-L	2012.03.02
H-D-S-Jr-035-L	2012.03.02
H-D-S-Jr-038-L	2012.03.02
H-D-S-Jr-C-025-L	2012.03.02
H-D-S-Jr-C-032-L	2012.03.02
H-D-S-Jr-C-035-L	2012.03.02
H-D-S-Jr-C-038-L	2012.03.02

Allowed Optional variants

A suffix **AAYY** can if needed be added at the end of the above listed REF numbers:
Purpose, handle national label requirements and identification of different distributors in specific countries

D is double ended Guide Wire – one end straight, **Jr** is the shape of the tip in mm (rad. 1,5-15mm)
one end Jr

025-038 is the diameter in inches.

H is stiff

L and **r** are variables in the standard article number.

r is the radius of the J tip in the range from 1,5 mm. to 15 mm.

C is PTFE coated

H-X is extra stiff

L is the total length of the guide wire in the range from 30 cm. to 450 cm.

Optional suffix handling national requirements:

AA is country abbreviation written with 2 characters.

YY is a number from 01 to 99 in cases were REF number is to identify specific distributors in specific countries.

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Seldinger Movable

REF Number	Date for first CE Mark
M-S-032-L	2012.03.02
M-S-035-L	2012.03.02
M-S-038-L	2012.03.02
M-S-C-032-L	2012.03.02
M-S-C-035-L	2012.03.02
M-S-C-038-L	2012.03.02
M-Jr-032-L	2012.03.02
M-Jr-035-L	2012.03.02
M-Jr-038-L	2012.03.02
M-Jr-C-032-L	2012.03.02
M-Jr-C-035-L	2012.03.02
M-Jr-C-038-L	2012.03.02
H-M-S-032-L	2012.03.02
H-M-S-035-L	2012.03.02
H-M-S-038-L	2012.03.02
H-M-S-C-032-L	2012.03.02
H-M-S-C-035-L	2012.03.02
H-M-S-C-038-L	2012.03.02
H-M-Jr-032-L	2012.03.02
H-M-Jr-035-L	2012.03.02
H-M-Jr-038-L	2012.03.02
H-M-Jr-C-032-L	2012.03.02
H-M-Jr-C-035-L	2012.03.02
H-M-Jr-C-038-L	2012.03.02

Allowed Optional variants

A suffix **AAYY** can if needed be added at the end of the above listed REF numbers:
Purpose, handle national label requirements and identification of different distributors in specific countries

M is a movable Guide Wire
Jr is the shape of the tip in mm (rad. 1,5-15mm)
C is PTFE coated
L and r are variables in the standard article number.
r is the radius of the J tip in the range from 1,5 mm. to 15 mm.

S (straight) is the shape of the tip
032-038 is the diameter in inches.
H is stiff
L is the total length of the guide wire in the range from 30 cm. to 450 cm.

Optional suffix handling national requirements:

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