Presafe®
A DNV GL COMPANY

Quality System Certificate

DANAK
SYSTEM Reg. No. 5007

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 692	aur7ai1910v270f524	2020-01-07	2023-01-07	2010-02-01

This is to certify that the quality system of:

Eldon Biologicals A/S
Sandtoften 10
2820 Gentofte
Denmark

fulfills the requirements in:

EN ISO 13485:2016

The certificate covers the following activities:

Manufacture and final testing of dry format cards and assembly of kits for in vitro diagnostic blood type determination

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

EC Type-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex V

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 491	aur7ai1911v281f542	2020-01-07	2020-11-06	2005-02-18

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

Eldon Biologicals A/S
Sandtoften 10
2820 Gentofte
Denmark

have been approved in conformity with the requirements of:

TS atitikimas

Annex V of Council Directive 98/79/EC concerning in vitro diagnostic medical devices as transposed into Danish law. The type conforms to the relevant provisions of the directive.

The certificate covers the following devices:

Dry format cards and kits for in vitro diagnostic blood type determination

The Type 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 device without the approval of Presafe Denmark A/S. The EC Type-Examination Certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" Council Directive 98/79/EC concerning in vitro diagnostic devices as transposed into Danish law. The certificate is based on successful type-examination in accordance with the IVDD, Annex V.

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

Heidi Jørgensen
Authorized person
For Presafe Denmark A/S

EC Type-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex V

A DNV GL COMPANY

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 491	aur7ai1911v281f542	2020-01-07	2020-11-06	2005-02-18

The following devices from Annex II, List A are covered by the certificate:

PRODUCT NAME	ELDONCARD TYPE	LANGUAGE VERSION	REF - NUMBER
ELDON BAG 2511-25	2511	EN	700-05
ELDON BAG 2511-30	2511	EN	700-06
ELDON BAG 2511-25	2511	RU	700-14
ELDON BAG 2511-25	2511	EN	700-16
ELDON BAG 2521-25	2521	EN	710-01
ELDON BAG 2521-25	2521	DA	710-02
ELDON BAG 2521-10	2521	EN	710-03
ELDON BAG 2521-25	2521	RU	710-04
ELDON BAG 2521-25	2521	HU	710-05
ELDON BAG 2521-25	2521	ES	710-06
ELDON BAG 2521-50	2521	EN	710-10
ELDON BAG 2521-25	2521	EN	710-11
ELDON BAG 2521-25	2521	EN	710-17
ELDON BAG 2521 ID-25	2521	EN	710-19
ELDON BAG 2521 ID-10	2521	EN	710-21
ELDON BAG 2551-25	2551	RU	730-01
ELDON BAG 2551-25	2551	ES	730-02
ELDON BAG 2551-25	2551	EN	730-05
ELDON BAG 2551v-25	2551	EN	730-07
ELDON BAG ID-25	ID	EN	770-00
ELDONBOX 2511-100	2511	DE	400-00
ELDONBOX 2511-100	2511	DA	400-01
ELDONBOX 2511-100	2511	EN	400-02
ELDONBOX 2511-100	2511	ES	400-04
ELDONBOX 2511-100	2511	RU	400-05
ELDONBOX 2521-100	2521	DE	410-00
ELDONBOX 2521-100	2521	RU	410-02
ELDONBOX 2521-100	2521	ES	410-03
ELDONBOX 2521-100	2521	HU	410-04
ELDONBOX 2521-100	2521	EN	410-05
ELDONBOX 2521 ID-100	2521	EN	410-07
ELDONBOX 2521-100	2521	EN	410-08
ELDONBOX 2551-100	2551	DE	430-00
ELDONBOX 2551-100	2551	EN	430-01
ELDONBOX 2551-100	2551	ES	430-02
ELDONBOX 2551-100	2551	RU	430-04
ELDONBOX 2551v-100	2551	EN, VI	430-06
ELDONBOX Rh-100	RhD	EN	460-00
ELDONBOX ID-100	ID	EN	470-00
ELDON EMERGENY PACK 2551-100	2551	EN	630-00
DOCTORS KIT DKS 2511-00	2511	EN	600-08
DOCTORS KIT DKS 2511-00	2511	EN	600-17
DOCTORS KIT DKS 2511-00	2511	ES	600-18
DOCTORS KIT DKS 2521-25	2521	EN	610-13
DOCTORS KIT DKS 2521-10	2521	EN	610-28
DOCTORS KIT DKS RhD-25	RhD	EN	660-01

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EC Type-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex V

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 491	**aur7ai1911v281f542**	**2020-01-07**	**2020-11-06**	**2005-02-18**

DOCTORS KIT DKS ID-25	ID	EN	670-05
ELDON MILITATY KIT MKS 2521-25	2521	EN	610-11
ELDON MILITATY KIT MKS 2521-25	2521	EN, RU	610-33
ONE MANKIT OKS 2511-1	2511	EN	500-08
ONE MANKIT OKS 2511-1	2511	FR	500-26

EC Certificate
Production Quality Assurance
Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex VII

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM-492	aur7ai1911v281f524	2020-01-07	2022-01-31	2005-02-18

This is to certify that the quality system of:

Eldon Biologicals A/S
Sandtoften 10
2820 Gentofte
Denmark

has been audited under the requirements of:

Annex VII of Council Directive 98/79/EC, as transposed into Danish law.
The quality system meets the requirements of the directive.
For the placing on the market of devices covered by this certificate an Annex V certificate is required.

The scope of the certification is:

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Manufacture and final testing of dry format cards and assembly of kits for in vitro diagnostic blood type determination

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the manufacturer does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S.
The EC certificate is issued in accordance with Presafe Denmark A/S' "General terms and conditions" cf. Council Directive 98/79/EC concerning in vitro diagnostic devices and entitles the certificate holder 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 IVDD, Annex VII, section 4.

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

Heidi Jørgensen
Authorized person
For Presafe Denmark A/S

EC Certificate
Production Quality Assurance
Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex VII

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM-492	aur7ai1911v281f524	2020-01-07	2022-01-31	2005-02-18

The following products from Annex II, list A are covered by this certificate (and by EC Type-Examination Certificate DGM - 491):

PRODUCT NAME	ELDONCARD TYPE	LANGUAGE VERSION	REF - NUMBER
ELDON BAG 2511-25	2511	EN	700-05
ELDON BAG 2511-30	2511	EN	700-06
ELDON BAG 2511-25	2511	RU	700-14
ELDON BAG 2511-25	2511	EN	700-16
ELDON BAG 2521-25	2521	EN	710-01
ELDON BAG 2521-25	2521	DA	710-02
ELDON BAG 2521-10	2521	EN	710-03
ELDON BAG 2521-25	2521	RU	710-04
ELDON BAG 2521-25	2521	HU	710-05
ELDON BAG 2521-25	2521	ES	710-06
ELDON BAG 2521-50	2521	EN	710-10
ELDON BAG 2521-25	2521	EN	710-11
ELDON BAG 2521-25	2521	EN	710-17
ELDON BAG 2521 ID-25	2521	EN	710-19
ELDON BAG 2521 ID-10	2521	EN	710-21
ELDON BAG 2551-25	2551	RU	730-01
ELDON BAG 2551-25	2551	ES	730-02
ELDON BAG 2551-25	2551	EN	730-05
ELDON BAG 2551v-25	2551	EN	730-07
ELDON BAG ID-25	ID	EN	770-00
ELDONBOX 2511-100	2511	DE	400-00
ELDONBOX 2511-100	2511	DA	400-01
ELDONBOX 2511-100	2511	EN	400-02
ELDONBOX 2511-100	2511	ES	400-04
ELDONBOX 2511-100	2511	RU	400-05
ELDONBOX 2521-100	2521	DE	410-00
ELDONBOX 2521-100	2521	RU	410-02
ELDONBOX 2521-100	2521	ES	410-03
ELDONBOX 2521-100	2521	HU	410-04
ELDONBOX 2521-100	2521	EN	410-05
ELDONBOX 2521 ID-100	2521	EN	410-07
ELDONBOX 2521-100	2521	EN	410-08
ELDONBOX 2551-100	2551	DE	430-00
ELDONBOX 2551-100	2551	EN	430-01
ELDONBOX 2551-100	2551	ES	430-02
ELDONBOX 2551-100	2551	RU	430-04
ELDONBOX 2551v-100	2551	EN, VI	430-06
ELDONBOX Rh-100	RhD	EN	460-00
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DOCTORS KIT DKS 2511-00	2511	ES	600-18
DOCTORS KIT DKS 2521-25	2521	EN	610-13
DOCTORS KIT DKS 2521-10	2521	EN	610-28
DOCTORS KIT DKS RhD-25	RhD	EN	660-01

TS atitikimas

EC Certificate
Production Quality Assurance
Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex VII

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM-492	**aur7ai1911v281f524**	**2020-01-07**	**2022-01-31**	**2005-02-18**

DOCTORS KIT DKS ID-25	ID	EN	670-05
ELDON MILITATY KIT MKS 2521-25	2521	EN	610-11
ELDON MILITATY KIT MKS 2521-25	2521	EN, RU	610-33
ONE MANKIT OKS 2511-1	2511	EN	500-08
ONE MANKIT OKS 2511-1	2511	FR	500-26