

EC- Declaration of Conformity according to annex III, EC Directive 98/79/EF

We declare under our sole responsibility that the product:

HR-TEST for Detection of Histamine

represented by part numbers:

PLATES / PANELS:

RLA212-inh	Inhalation Panel
RLA213-food	Food Panel
RLA214-der	Derma Panel
RLA223-food	Food Asia Panel
RLA222-inh	Inhalation Asia Panel
RLA800-CD	Customer Designed
RLA211-CM	Customer Material
RLA5-CIU	HR-Urticaria Test Kit

STRIP FORMATS

RLA5-Xxxx	Various allergens
RLA5CM	Customer material
RLA120	Various allergens
RLA120CM	Customer material
RLA500	Preparation vial

HISTAREADERS & REAGENTS:

RLA700	HR-Test Reagent Kit HISTAREADER™
RLA216	Calibration
RLA501	HISTAREADER™ 501
RLA501-1	HISTAREADER™ 501-1

BULK REAGENTS FOR SUPPLEMENT

RLA701	Stripping Buffer 100 mL Panel	RLA705	Detergent 100 mL
RLA702	Diluent, 1000 mL	RLA706	Pipes buffer, 1000 mL
RLA703	Stop Solution, 1000 mL	RLA708	OPA Discs 25 mg 10 pcs
RLA704	HClO ₄ , 7%, 10 mL	RLA709	Acidious Clean for Histareader, 100 mL
		RLR007W	Wash Buffer, 200 mL

STRIPS (Single allergens)

F069 Almond	F043 Lamb	F071Walnut	M009 Alternaria alternata
F054 Banana	F047 Mackerel	F013 Wheat flour	M035 Aspergillus fumigatus
F067 Barley	F081 Melon	P026 Alder	M077 Aspergillus versicolor
F041 Beef	F011 Milk	P028 Ash	M022 Baker's yeast
F079 Blue mussel	F063 Oat	P027 Elm	M037 Botrytis cinerea
F070 Brazil nut	F080 Octopus	P025 Hazel	M024 Candida albicans
F065 Buckwheat	F052 Orange	P003 Mugwort	M010 Cladosporium herbarum
F056 Carrot	F015 Peanut	P083 Ragweed	M007 Derm pteronyssinus
F019 Celery	F060 Pepper	P001 Silver birch	M008 Derm farinae
F044 Chicken	F045 Plaice	P002 Timothy grass	M038 Penicillium expansum
F072 Cocoa	F042 Pork	P100 Platanus acerifolia	M039 Penicillium chrysogenum
F016 Cod Fish	F057 Potato	P101 Japanese hop	M021 Pityrosporum ovale
F066 Corn	F068 Rice	E006 Cat epithelia	M040 Trichoderma viride
F048 Crab	F064 Rye	E082 Cockroach	M102 Blomia tropicalis
F012 Egg white	F078 Salmon	E005 Dog epithelia	V073 Bee venom
F059 Green bean	F017 Shrimp	E033 Guinea pig epithelia	V074 Wasp venom
F061 Green pea	F018 Soybean	E032 Hamster epithelia	O075 Latex
F014 Hazelnut	F053 Strawberry	E004 Horse epithelia	CM-S Customer material
F046 Herring	F058 Tomato	E031 Rabbit epithelia	
F020 Kiwi	F049 Tuna	E030 Rat epithelia	

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classification according to Annex II, IVDD: Common class

has been designed and manufactured to the harmonized standards:

Directive 98/79/EF

EN ISO 13485 Medical devices, quality management systems, requirements for regulatory purposes.
(EN ISO 13485 application of EN ISO 9001)

EN ISO 14971 Medical devices- Application of risk management to medical devices (ISO 14971:2012)

EN ISO 18113-2 In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part2:
In vitro diagnostic reagent for professional use (ISO 18113-2:2011)

EN ISO 15223-1 Medical devices - Symbols to be used with medical device labels, labelling and information to be
supplied - Part 1: General requirements (ISO 15223-1 : 2012)

All concerned devices produced after

06JAN2013

are placed on the market in accordance with this declaration.

Copenhagen, 22. April 2015

A handwritten signature in blue ink, appearing to be 'Lise Bo', is written over a horizontal line.

Signature
Lise Bo - Quality Manager