

EC Declaration of Conformity

Manufacturer Name:	RefLab Aps
Manufacturer Address:	Kanalholmen 1, 2.th DK-2650 Hvidovre Denmark
Notified Body name:	N/A
Notified Body Address:	N/A
Notified Body Identification number:	N/A

Reflab Aps hereby declares conformity to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices for the following In Vitro Diagnostic Devices:

Art. no	Name of device	Pack size	Art. no	Name of device	Pack size
RLA211	CM-plate	1	RLA211.10	CM-plate	10
RLA212	Inhalation allergen panel	1	RLA212.10	Inhalation allergen panel	10
RLA213	Food allergen panel	1	RLA213.10	Food allergen panel	10
RLA214	Dermatology allergen panel	1	RLA214.10	Dermatology allergen panel	10
RLA215	Fungi allergen panel	1	RLA215.10	Fungi allergen panel	10
RLA220	Fruit-Vegetable allergen panel	1	RLA220.10	Fruit-Vegetable allergen panel	10
RLA221	Grain, Flour & Nut allergen panel	1	RLA221.10	Grain, Flour & Nut allergen panel	10
RLA222	Inhalation Asian allergen panel	1	RLA222.10	Inhalation Asian allergen panel	10
RLA223	Food Asia allergen panel	1	RLA223.10	Food Asia allergen panel	10
RLA5-CSU	s-BHRA (HR-Urticaria Test kit)	1			
RLA800	Customer Designed panel variant *	1	RLA800.10	Customer Designed panel variant *	10

*) List of available allergens for panel variants:

F069 Almond	F043 Lamb	F058 Tomato	M009 Alternaria alternata
F054 Banana	F047 Mackerel	F049 Tuna	M035 Aspergillus fumigatus
F067 Barley	F086 Mango	F071 Walnut	M077 Aspergillus versicolor
F041 Beef	F081 Melon	F013 Wheat flour	M022 Baker's yeast
F070 Brazil nut	F011 Milk	P026 Alder	M037 Botrytis cinerea
F065 Buckwheat	F063 Oat	P028 Ash	M024 Candida albicans
F056 Carrot	F080 Octopus	P025 Hazel	M010 Cladosporium herbarum
F089 Cashew nut	F052 Orange	P085 Japanese hop	M007 Derm pteronyssinus
F019 Celery	F087 Peach	P003 Mugwort	M008 Derm farinae
F044 Chicken	F015 Peanut	P100 Platanus acerifolia	M038 Penicillium expansum
F090 Clam	F060 Pepper	P083 Ragweed	M039 Penicillium chrysogenum
F072 Cocoa	F045 Plaice	P001 Silver birch	M021 Pityrosporum ovale
F016 Cod Fish	F042 Pork	P002 Timothy grass	M040 Trichoderma viride
F066 Corn	F057 Potato	E006 Cat epithelia	V073 Bee venom
F048 Crab	F068 Rice	E082 Cockroach	V074 Wasp venom
F012 Egg white	F064 Rye	E005 Dog epithelia	O075 Latex
F059 Green bean	F078 Salmon	E033 Guinea pig epithelia	
F061 Green pea	F088 Sesame	E032 Hamster epithelia	
F014 Hazelnut	F017 Shrimp	E004 Horse epithelia	
F046 Herring	F018 Soybean	E031 Rabbit epithelia	
F020 Kiwi	F053 Strawberry	E030 Rat epithelia	

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Art. no	Name of device
RLA501	Histareader501 w/ Software version v3.0-0612
RLA501-1	Histareader501-1 w/ Software version v12-0612

This declaration of conformity is issued under the sole responsibility of RefLab Aps. We hereby declare that the in-vitro diagnostic medical device(s) specified above meet the provision of the EC Directive 98/79/EF, Annex III (IVDD). This declaration is supported by the ISO 13485 Quality Management System approval issued by Bureau Veritas. All supporting documentation is retained at the premises of the manufacturer.

Signature:



Randi Lundberg

Chief Operating Officer & Quality
Manager

Place and date (dd-mm-yyyy) of issue:

Hvidovre, 12-Apr-2024