

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

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

Hvidovre, 17-Nov-2023