

EU Declaration of Conformity



We hereby declare that the products described below conform to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

Legal Manufacturer: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

EU Authorized Representative: Siemens Healthcare Diagnostics Manufacturing Ltd.
Chapel Lane
Swords, Co. Dublin, Ireland

Product Names: See *List of Products*

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: DOC_Food Allergens

Version: 4.0

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.
This declaration supersedes any declaration issued previously for the same product.*

Signature: _____ 2019-02-25

Malgorzata Robak
Regulatory Affairs Supervisor
Siemens Healthcare Diagnostics Products Ltd.
Llanberis, Gwynedd, LL55 4EL, UK

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

EU Declaration of Conformity

List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulin 2000 Alaskan Pollock Roe Specific Allergen	F350L2	10639220
Immulin 2000 Almond Specific Allergen	F20L2	10385714
Immulin 2000 Alpha Lactalbumin Specific Allergen	F76L4	10385849
Immulin 2000 Anchovy Specific Allergen	F313L2	10385792
Immulin 2000 Anise Specific Allergen	F271L2	10385763
Immulin 2000 Apple Specific Allergen	F49L4	10385832
Immulin 2000 Apricot Specific Allergen	F237L2	10385738
Immulin 2000 Argula Specific Allergen	F406L2	10385821
Immulin 2000 Artichoke Specific Allergen	F358L2	10385808
Immulin 2000 Asparagus Specific Allergen	F261L2	10385755
Immulin 2000 Avocado Specific Allergen	F96L2	10385875
Immulin 2000 Baker's Yeast Specific Allergen	F45L2	10385828
Immulin 2000 Bamboo Shoot Specific Allergen	F51L2	10639223
Immulin 2000 Banana Specific Allergen	F92L2	10385871
Immulin 2000 Barley Specific Allergen	F6L2	10385845
Immulin 2000 Basil Specific Allergen	F269L2	10385760
Immulin 2000 Bay Leaf Specific Allergen	F278L2	10385768
Immulin 2000 Beef Specific Allergen	F27L2	10385770
Immulin 2000 Beta Lactoglobulin Specific Allergen	F77L4	10385851
Immulin 2000 Black Pepper Specific Allergen	F280L2	10385771
Immulin 2000 Blue Mussel Specific Allergen	F37L2	10385812
Immulin 2000 Blueberry Specific Allergen	F288L2	10385776
Immulin 2000 Boiled Milk Specific Allergen	F231L2	10385731
Immulin 2000 Brazil Nut Specific Allergen	F18L2	10385701
Immulin 2000 Brewer's Yeast Specific Allergen	F403L2	10385818
Immulin 2000 Broccoli Specific Allergen	F260L2	10385754
Immulin 2000 Brussel Sprout Specific Allergen	F217L2	10385721
Immulin 2000 Buckwheat Specific Allergen	F11L2	10385689
Immulin 2000 Cabbage Specific Allergen	F216L2	10385720
Immulin 2000 Cacao Specific Allergen	F93L2	10385872
Immulin 2000 Cantaloupe Specific Allergen	F102L2	10385685
Immulin 2000 Caraway Specific Allergen	F265L2	10385758
Immulin 2000 Carrot Specific Allergen	F31L4	10385797
Immulin 2000 Casein Specific Allergen	F78L4	10385853
Immulin 2000 Cashew Specific Allergen	F202L2	10385706
Immulin 2000 Cauliflower Specific Allergen	F291L2	10385779

EU DECLARATION OF CONFORMITY

EU Declaration of Conformity

EU DECLARATION OF CONFORMITY

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulin 2000 Cayenne Pepper Specific Allergen	F19L2	10385702
Immulin 2000 Celery Specific Allergen	F85L2	10385862
Immulin 2000 Cheese, Cheddar Specific Allergen	F81L2	10385858
Immulin 2000 Cheese, mold type Specific Allergen	F82L2	10385859
Immulin 2000 Cherry Specific Allergen	F242L2	10385740
Immulin 2000 Chestnut Specific Allergen	F299L2	10385782
Immulin 2000 Chick Pea Specific Allergen	F309L2	10385790
Immulin 2000 Chicken Meat Specific Allergen	F83L2	10385860
Immulin 2000 Chilipepper Specific Allergen	F279L2	10385769
Immulin 2000 Chocolate Specific Allergen	F105L2	10385686
Immulin 2000 Chub Mackerel Specific Allergen	F50L2	10385835
Immulin 2000 Cinnamon Specific Allergen	F220L2	10385725
Immulin 2000 Clam Specific Allergen	F207L2	10385711
Immulin 2000 Clove Specific Allergen	F268L2	10385759
Immulin 2000 Coconut Specific Allergen	F36L2	10385811
Immulin 2000 Codfish Specific Allergen	F3L4	10385815
Immulin 2000 Coffee Specific Allergen	F221L2	10385726
Immulin 2000 Common Millet Specific Allergen	F55L2	10385837
Immulin 2000 Coriander Specific Allergen	F317L2	10385795
Immulin 2000 Corn Specific Allergen	F8L4	10385868
Immulin 2000 Crab Specific Allergen	F23L2	10385739
Immulin 2000 Cranberry Specific Allergen	F341L2	10385804
Immulin 2000 Crayfish Specific Allergen	F320L2	10385798
Immulin 2000 Cucumber Specific Allergen	F244L2	10385741
Immulin 2000 Curry Specific Allergen	F281L2	10385772
Immulin 2000 Date Specific Allergen	F289L2	10385777
Immulin 2000 Dill Specific Allergen	F277L2	10385767
Immulin 2000 Egg Specific Allergen	F245L2	10385742
Immulin 2000 Egg White Specific Allergen	F1L4	10385704
Immulin 2000 Egg Yolk Specific Allergen	F75L4	10385847
Immulin 2000 Eggplant Specific Allergen	F262L2	10385756
Immulin 2000 Fennel Seeds Specific Allergen	F219L2	10385723
Immulin 2000 Fig Specific Allergen	F402L2	10385817
Immulin 2000 Flounder Specific Allergen	F147L2	10385693
Immulin 2000 Food Panel 1 Specific Allergen	FP1L4	10385882
Immulin 2000 Food Panel 13 Specific Allergen	FP13L4	10385878
Immulin 2000 Food Panel 15 Specific Allergen	FP15L4	10385880

EU Declaration of Conformity

EU DECLARATION OF CONFORMITY

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulin 2000 Food Panel 2 Specific Allergen	FP2L4	10385889
Immulin 2000 Food Panel 24 Specific Allergen	FP24L4	10385883
Immulin 2000 Food Panel 25 Specific Allergen	FP25L4	10385884
Immulin 2000 Food Panel 26 Specific Allergen	FP26L4	10385885
Immulin 2000 Food Panel 27 Specific Allergen	FP27L4	10385886
Immulin 2000 Food Panel 28 Specific Allergen	FP28L4	10385887
Immulin 2000 Food Panel 3 Specific Allergen	FP3L4	10385891
Immulin 2000 Food Panel 4 Specific Allergen	FP4L4	10635711
Immulin 2000 Food Panel 5 Specific Allergen	FP5L4	10385897
Immulin 2000 Food Panel 50 Specific Allergen	FP50L4	10385893
Immulin 2000 Food Panel 51 Specific Allergen	FP51L4	10385895
Immulin 2000 Food Panel 6 Specific Allergen	FP6L4	10385899
Immulin 2000 Food Panel 7 Specific Allergen	FP7L4	10385903
Immulin 2000 Food Panel 73 Specific Allergen	FP73L4	10385901
Immulin 2000 Food Panel 8 Specific Allergen	FP8L4	10368604
Immulin 2000 Foxtail Millet Specific Allergen	F56L2	10385838
Immulin 2000 Garlic Specific Allergen	F47L2	10385829
Immulin 2000 Ginger Specific Allergen	F270L2	10385762
Immulin 2000 Gluten Specific Allergen	F79L4	10385855
Immulin 2000 Goat Milk Specific Allergen	F409L2	10385823
Immulin 2000 Grape Specific Allergen	F259L2	10385751
Immulin 2000 Grapefruit Specific Allergen	F209L2	10385713
Immulin 2000 Green Bean Specific Allergen	F315L2	10385794
Immulin 2000 Green Olive Specific Allergen	F223L2	10385728
Immulin 2000 Green Pea Specific Allergen	F12L2	10385690
Immulin 2000 Green Pepper Specific Allergen	F263L2	10385757
Immulin 2000 Haddock Specific Allergen	F42L2	10385826
Immulin 2000 Halibut Specific Allergen	F303L2	10385788
Immulin 2000 Hazelnut Specific Allergen	F17L4	10385699
Immulin 2000 Herring Specific Allergen	F205L2	10385709
Immulin 2000 Honey Specific Allergen	F247L2	10385743
Immulin 2000 Horseradish Specific Allergen	F375L2	10368603
Immulin 2000 Jack Mackerel, Scad Specific Allergen	F60L2	10639218
Immulin 2000 Kiwi Fruit Specific Allergen	F84L2	10385861
Immulin 2000 Lamb Specific Allergen	F88L2	10385865
Immulin 2000 Lemon Specific Allergen	F208L2	10385712
Immulin 2000 Lentil Specific Allergen	F235L2	10385736

EU Declaration of Conformity

EU DECLARATION OF CONFORMITY

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulin 2000 Lettuce Specific Allergen	F215L2	10385719
Immulin 2000 Lima Bean Specific Allergen	F182L2	10385700
Immulin 2000 Lime Specific Allergen	F306L2	10385789
Immulin 2000 Lobster Specific Allergen	F80L2	10385857
Immulin 2000 Loquat Specific Allergen	F401L2	10385816
Immulin 2000 Lupine Specific Allergen	F335L2	10471070
Immulin 2000 Macadamia Specific Allergen	F345L2	10360581
Immulin 2000 Mackrel Specific Allergen	F206L2	10385710
Immulin 2000 Malt Specific Allergen	F90L2	10385869
Immulin 2000 Mandarin (Tangerine) Specific Allergen	F302L2	10385787
Immulin 2000 Mango Specific Allergen	F91L2	10385870
Immulin 2000 Marjoram Specific Allergen	F274L2	10385766
Immulin 2000 Melon Specific Allergen	F87L2	10385864
Immulin 2000 Milk Specific Allergen	F2L4	10385784
Immulin 2000 Mint Specific Allergen	F405L2	10385820
Immulin 2000 Mushroom Specific Allergen	F212L2	10385716
Immulin 2000 Mustard Specific Allergen	F89L2	10385866
Immulin 2000 nPen m Specific Allergen	F351L2	10385807
Immulin 2000 Nutmeg Specific Allergen	F282L2	10360582
Immulin 2000 Oat Specific Allergen	F7L2	10385856
Immulin 2000 Octopus Specific Allergen	F59L2	10385840
Immulin 2000 Onion Specific Allergen	F48L2	10385830
Immulin 2000 Orange Specific Allergen	F33L4	10385803
Immulin 2000 Oregano Specific Allergen	F283L2	10385773
Immulin 2000 Ovalbumin Specific Allergen	F232L2	10385732
Immulin 2000 Ovomuroid Specific Allergen	F233L2	10385733
Immulin 2000 Oyster Specific Allergen	F290L2	10385778
Immulin 2000 Pacific Squid Specific Allergen	F58L4	10639216
Immulin 2000 Papaya Specific Allergen	F293L2	10385780
Immulin 2000 Paprika Specific Allergen	F218L2	10385722
Immulin 2000 Parmesan Cheese Specific Allergen	F67L2	10385844
Immulin 2000 Parsley Specific Allergen	F86L2	10385863
Immulin 2000 Passion Fruit Specific Allergen	F294L2	10385781
Immulin 2000 Peach Specific Allergen	F95L2	10385874
Immulin 2000 Peanut Specific Allergen	F13L4	10385692
Immulin 2000 Pear Specific Allergen	F94L2	10385873
Immulin 2000 Pecan Nut Specific Allergen	F201L2	10385705

EU Declaration of Conformity

EU DECLARATION OF CONFORMITY

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulin 2000 Perch Specific Allergen	F65L2	10385843
Immulin 2000 Persimmon Specific Allergen	F301L2	10385786
Immulin 2000 Pine Nut Specific Allergen	F253L2	10385746
Immulin 2000 Pineapple Specific Allergen	F210L2	10385715
Immulin 2000 Pinto Bean Specific Allergen	F300L2	10385785
Immulin 2000 Pistachio Specific Allergen	F203L2	10385707
Immulin 2000 Plaice Specific Allergen	F254L2	10385747
Immulin 2000 Plum Specific Allergen	F255L2	10385748
Immulin 2000 Poppy Seed Specific Allergen	F224L2	10385729
Immulin 2000 Pork Specific Allergen	F26L2	10385761
Immulin 2000 Potato Specific Allergen	F35L2	10385809
Immulin 2000 Pumpkin Specific Allergen	F225L2	10385730
Immulin 2000 Rabbit Specific Allergen	F213L2	10385717
Immulin 2000 Radish Specific Allergen	F119L2	10385688
Immulin 2000 Raspberry Specific Allergen	F343L2	10385805
Immulin 2000 Red Kidney Bean Specific Allergen	F287L2	10385775
Immulin 2000 Red Snapper Specific Allergen	F381L2	10385813
Immulin 2000 Rice Specific Allergen	F9L4	10385877
Immulin 2000 Rye Specific Allergen	F5L2	10385841
Immulin 2000 Sage Specific Allergen	F344L2	10385806
Immulin 2000 Salmon Roe Specific Allergen	F349L4	10639217
Immulin 2000 Salmon Specific Allergen	F41L2	10385825
Immulin 2000 Sardine Specific Allergen	F61L2	10385842
Immulin 2000 Scallop Specific Allergen	F338L2	10385801
Immulin 2000 Sesame Seed Specific Allergen	F10L2	10385687
Immulin 2000 Sheep's Milk Specific Allergen	F325L2	10368602
Immulin 2000 Shrimp Specific Allergen	F24L4	10385745
Immulin 2000 Snail Specific Allergen	F314L2	10385793
Immulin 2000 Sole Specific Allergen	F337L2	10385800
Immulin 2000 Soybean Specific Allergen	F14L4	10385695
Immulin 2000 Spinach Specific Allergen	F214L2	10385718
Immulin 2000 Squid Specific Allergen	F258L2	10385750
Immulin 2000 Strawberry Specific Allergen	F44L2	10385827
Immulin 2000 Sugar Cane Specific Allergen	F21L2	10385724
Immulin 2000 Sweet Potato Specific Allergen	F54L2	10385836
Immulin 2000 Swiss Cheese Specific Allergen	F170L2	10385697
Immulin 2000 Swordfish Specific Allergen	F312L2	10385791

EU Declaration of Conformity

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulin 2000 Tarragon Specific Allergen	F272L2	10385764
Immulin 2000 Tea Specific Allergen	F222L2	10385727
Immulin 2000 Thyme Specific Allergen	F273L2	10385765
Immulin 2000 Tomato Specific Allergen	F25L4	10385753
Immulin 2000 Trout Specific Allergen	F204L2	10385708
Immulin 2000 Tuna Specific Allergen	F40L2	10385824
Immulin 2000 Turkey Meat Specific Allergen	F284L2	10385774
Immulin 2000 Vanilla Specific Allergen	F234L2	10385735
Immulin 2000 Walnut Specific Allergen	F256L2	10385749
Immulin 2000 Watermelon Specific Allergen	F329L2	10385799
Immulin 2000 Wheat Specific Allergen	F4L4	10385834
Immulin 2000 Whey Specific Allergen	F236L2	10385737
Immulin 2000 White Bean Specific Allergen	F15L2	10385696
Immulin 2000 Whiting Specific Allergen	F408L2	10385822
Immulin 2000 Yam Specific Allergen	F97L2	10639222
Immulin 2000 Yogurt Specific Allergen	F360L2	10385810