

Siemens Healthcare Diagnostics Products Limited.
Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, UK

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To whom it may concern,

We, **Siemens Healthcare Diagnostics Products Limited.**, located at Glyn Rhonwy, Llanberis, Gwynedd, LL55 4EL, United Kingdom as the product owner, hereby declares that the medical devices mentioned in Attachment 1 comply to the below standards.

List of Standards Applied:

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices (ISO 14971:2007)
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016, Corrected version 2016-12-15)
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)

EN ISO 23640:2015	In vitro diagnostic medical devices -- Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366:2008	Medical devices -- Application of usability engineering to medical devices (IEC 62366:2007/A1:2014)
EN 62366-1:2015	Medical devices – Part 1: Application of usability engineering to medical devices

[Signature & Seal]
[Name] Oi Yan Lam
[Title] Regulatory Affairs Manager

Signature: 

*Electronically signed by: Oi Yan Lam
Reason: I am approving this document
Date: Aug 11, 2022 17:45 GMT+1*

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Attachment 1

Siemens Material Number	Part Number	Product Description
10360576	A345L2	IMMULITE 2000 Specific Allergen nFel d 1
10385657	E72L2	IMMULITE 2000 Specific Allergen Mouse Urine e72
10385659	E74L2	IMMULITE 2000 Specific Allergen Rat Urine e74
10385661	E76L2	IMMULITE 2000 Specific Allergen Mouse Serum Proteins e76
10385689	F11L2	IMMULITE 2000 Specific Allergen Buckwheat f11
10385690	F12L2	IMMULITE 2000 Specific Allergen Green Pea f12
10385812	F37L2	IMMULITE 2000 Specific Allergen Blue Mussel f37
10385835	F50L2	IMMULITE 2000 Specific Allergen Chub Mackerel f50
10385837	F55L2	IMMULITE 2000 Specific Allergen Common Millet f55
10385857	F80L2	IMMULITE 2000 Specific Allergen Lobster f80
10385875	F96L2	IMMULITE 2000 Specific Allergen Avocado f96
10385705	F201L2	IMMULITE 2000 Specific Allergen Pecan Nut f201
10385706	F202L2	IMMULITE 2000 Specific Allergen Cashew f202
10385707	F203L2	IMMULITE 2000 Specific Allergen Pistachio f203
10385708	F204L2	IMMULITE 2000 Specific Allergen Trout f204
10385710	F206L2	IMMULITE 2000 Specific Allergen Mackerel f206
10385711	F207L2	IMMULITE 2000 Specific Allergen Clam f207
10385749	F256L2	IMMULITE 2000 Specific Allergen Walnut f256
10385755	F261L2	IMMULITE 2000 Specific Allergen Asparagus f26
10385778	F290L2	IMMULITE 2000 Specific Allergen Oyster f290
10385782	F299L2	IMMULITE 2000 Specific Allergen Chestnut f299
10385798	F320L2	IMMULITE 2000 Specific Allergen Crayfish f320
10360581	F345L2	IMMULITE 2000 Specific Allergen Macadamia Nut
10385817	F402L2	IMMULITE 2000 Specific Allergen Fig f402
10360574	A310L2	IMMULITE 2000 Specific Allergen nDer p 1
10360575	A316L2	IMMULITE 2000 Specific Allergen nDer p 2
10368597	A89L2	IMMULITE 2000 Specific Allergen nBet v 1, a89
10386083	T2L4	IMMULITE 2000 Specific Allergen Alder t2
10386098	T5L2	IMMULITE 2000 Specific Allergen Beech t5
10386056	T10L2	IMMULITE 2000 Specific Allergen Walnut Pollen t10
10386077	T22L2	IMMULITE 2000 Specific Allergen Pecan t22