

**EC DECLARATION OF CONFORMITY**

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**Ref. No: DC EliA/27****Phadia AB, Rapskatan 7P, P.O. Box 6460, 751 37 Uppsala, Sweden**

hereby declare that the products listed below fulfil the requirements in the "Directive 98/79/EC of the European parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices" (IVDD), the Swedish Medical Devices Act (1993:584) and the regulation LVFS 2001:7. The products are classified as "General devices" (all devices other than those covered by IVDD Annex II and self-testing devices). Conformity assessment is performed according to IVDD Annex III.

<b>Art. No.</b>	<b>Product Name</b>
14-5500-01	EliA dsDNA Well
14-5501-01	EliA U1RNP Well
14-5502-01	EliA Sm Well
14-5503-01	EliA Ro Well
14-5504-01	EliA La Well
14-5505-01	EliA CENP Well
14-5506-01	EliA Scl-70 Well
14-5507-01	EliA Jo-1 Well
14-5508-01	EliA Symphony Well
14-5509-01	EliA IgG Calibrator Well
14-5510-01	EliA Dummy Well
14-5511-01	EliA RNP70 Well
14-5512-01	EliA PR3 Well
14-5513-01	EliA MPO Well
14-5514-01	EliA GBM Well
14-5515-01	EliA CCP Well
14-5516-01	EliA IgA Calibrator Well
14-5517-01	EliA Celikey IgA Well
14-5518-01	EliA Celikey IgG Well
14-5519-01	EliA Gliadin IgA Well
14-5520-01	EliA Gliadin IgG Well
14-5521-01	EliA Rib-P Well

25.02.2015

Date



Manuela Hog, Regulatory Affairs Manager

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<b>Art. No.</b>	<b>Product Name</b>
14-5525-01	EliA Ro60 Well
14-5527-01	EliA IgM Calibrator Well
14-5528-01	EliA Cardiolipin IgA Well
14-5529-01	EliA Cardiolipin IgG Well
14-5530-01	EliA Cardiolipin IgM Well
14-5531-01	EliA $\beta$ 2-Glycoprotein I IgA Well
14-5532-01	EliA $\beta$ 2-Glycoprotein I IgG Well
14-5533-01	EliA $\beta$ 2-Glycoprotein I IgM Well
14-5535-01	EliA Anti-IgA Well
14-5536-01	EliA PR3 <sup>S</sup> Well
14-5537-01	EliA MPO <sup>S</sup> Well
14-5538-01	EliA Gliadin <sup>DP</sup> IgA Well
14-5539-01	EliA Gliadin <sup>DP</sup> IgG Well
14-5596-01	EliA CTD Screen Well
14-5598-01	EliA Ro52 Well
14-5599-01	EliA RNA Pol III Well
14-5600-01	EliA RF IgM Well
14-5601-01	EliA RF IgA Well
14-5602-01	EliA PM-Scl Well
14-5603-01	EliA PCNA Well
14-5604-01	EliA Mi-2 Well
14-5605-01	EliA Fibrillarin Well
14-5610-01	EliA Calprotectin Well
14-5615-01	EliA CCP IgA Well
14-5617-01	EliA RF IgG Well
14-5618-01	EliA Calprotectin Calibrator Well
14-5624-01	EliA SmD <sup>P</sup> Well
14-5629-01	EliA ssDNA Well
14-5633-01	EliA ASCA IgA Well
14-5635-01	EliA ASCA IgG Well
14-5637-01	EliA Scl-70 <sup>S</sup> Well
14-5638-01	EliA Stool Extraction Kit
14-5641-01	EliA anti-TPO Well
14-5642-01	EliA anti-TG Well
14-5649-01	EliA M2 Well

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<b>Art. No.</b>	<b>Product Name</b>
14-5651-01	EliA Stool Extraction Kit 2
14-5667-01	EliA Calprotectin 2 Calibrator Well
14-6748-01	EliA Calprotectin 2 Well
83-1000-01	EliA IgG Calibrators
83-1001-01	EliA IgG Curve Control
83-1002-01	EliA IgG Conjugate
83-1003-01	EliA Sample Diluent
83-1005-01	EliA IgG Conjugate
83-1010-01	EliA IgA Curve Control
83-1012-01	EliA IgA Conjugate
83-1013-01	EliA IgA Calibrators
83-1014-01	EliA IgA Conjugate
83-1015-01	EliA IgG Calibrator Strips
83-1016-01	EliA IgG Curve Control Strips
83-1017-01	EliA IgG Conjugate 50
83-1018-01	EliA IgG Conjugate 200
83-1019-01	EliA IgA Calibrator Strips
83-1020-01	EliA IgA Curve Control Strips
83-1021-01	EliA IgA Conjugate 50
83-1022-01	EliA IgA Conjugate 200
83-1023-01	EliA Sample Diluent
83-1031-01	EliA IgM Conjugate
83-1033-01	EliA ANA Positive Control 250
83-1034-01	EliA ANCA/GBM Positive Control 250
83-1035-01	EliA CCP Positive Control 250
83-1036-01	EliA Celiac Positive Control 250
83-1037-01	EliA IgG/IgM/IgA Negative Control 250
83-1038-01	EliA ANA Positive Control 100
83-1039-01	EliA ANCA/GBM Positive Control 100
83-1040-01	EliA CCP Positive Control 100
83-1041-01	EliA Celiac Positive Control 100
83-1042-01	EliA IgG/IgM/IgA Negative Control 100
83-1048-01	EliA IgM Conjugate
83-1049-01	EliA IgM Calibrators
83-1050-01	EliA IgM Curve Control
83-1051-01	EliA IgM Conjugate 50

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<b>Art. No.</b>	<b>Product Name</b>
83-1052-01	EliA IgM Calibrator Strips
83-1053-01	EliA IgM Curve Control Strips
83-1054-01	EliA APS Positive Control 100
83-1055-01	EliA APS Positive Control 250
83-1058-01	EliA Calprotectin Calibrators
83-1059-01	EliA Calprotectin Curve Control
83-1060-01	EliA Calprotectin Conjugate
83-1061-01	EliA Calprotectin Conjugate
83-1062-01	EliA Calprotectin Calibrator Strips
83-1063-01	EliA Calprotectin Curve Control Strips
83-1064-01	EliA Calprotectin Conjugate 50
83-1065-01	EliA Calprotectin Conjugate 200
83-1066-01	EliA Calprotectin Positive Control 100
83-1067-01	EliA Calprotectin Negative Control 100
83-1068-01	EliA Calprotectin Extraction Buffer
83-1069-01	EliA RF Positive Control 100
83-1070-01	EliA RF Positive Control 250
83-1071-01	EliA Sample Diluent
83-1072-01	EliA IgM Conjugate 200
83-1073-01	EliA ANA Positive Control 2500/5000
83-1074-01	EliA IgG/IgM/IgA Negative Control 2500/5000
83-1075-01	EliA ANCA/GBM Positive Control 2500/5000
83-1076-01	EliA CCP Positive Control 2500/5000
83-1077-01	EliA Celiac Positive Control 2500/5000
83-1078-01	EliA APS Positive Control 2500/5000
83-1079-01	EliA Anti-IgA Positive Control 100
83-1080-01	EliA Anti-IgA Positive Control 250
83-1083-01	EliA Calprotectin Positive Control 250
83-1084-01	EliA Calprotectin Positive Control 2500/5000
83-1085-01	EliA Calprotectin Negative Control 250
83-1086-01	EliA Calprotectin Negative Control 2500/5000
83-1087-01	EliA RF Positive Control 2500/5000
83-1103-01	EliA M2 Positive Control 100
83-1104-01	EliA M2 Positive Control 250
83-1105-01	EliA M2 Positive Control 2500/5000
83-1106-01	EliA ASCA Positive Control 100

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<b>Art. No.</b>	<b>Product Name</b>
83-1107-01	EliA ASCA Positive Control 250
83-1108-01	EliA ASCA Positive Control 2500/5000
83-1113-01	EliA Thyroid Positive Control 250
83-1114-01	EliA Thyroid Positive Control 2500/5000
83-1123-01	EliA Calprotectin 2 Calibrator Strips
83-1127-01	EliA Calprotectin 2 Conjugate 50
83-1128-01	EliA Calprotectin 2 Conjugate 200
83-1129-01	EliA Calprotectin 2 Curve Control Strips
83-1141-01	EliA ssDNA Positive Control 100
83-1142-01	EliA ssDNA Positive Control 250
83-1143-01	EliA ssDNA Positive Control 2500/5000
83-1147-01	EliA Calprotectin 2 Extraction Buffer

**END OF LIST**