





We Apply Science

D-tek EC Registration, p. 1 of 9

EC Declaration of Conformity according to Annex III of the In Vitro Diagnostic Directive (IVDD)

This is to certify that the IVD products listed in attachment are manufactured by: 

- These products comply with all essential requirements (Annex I) of the EC Directive 98/79/EC on In Vitro Diagnostic Medical Devices.
This compliance has been properly documented using a checklist created from Annex I of the IVDD, linked to all supporting technical documentation. This documentation included both product specific and process (Quality System) specific documents.
-  has a Quality System in place based on ISO 13485.
- This Declaration of Conformity is signed below, certifying that the requirements of IVD Directive 98/79/EC have been met and documented.

Date: 04/07/2024

Benoît Autem

Managing Director

M : +32 474 65 45 89

T : +32 65 32 97 51

bautem@d-tek.be

D-tek s.a.



Parc Initialis

Rue René Descartes, 19

BE - 7000 Mons

+32 65 84 18 88



We Apply Science

D-tek EC Registration, p. 2 of 9

CE REGISTRATIONS
IVDD 98/79/EC – Art. 10

METHODOLOGY: IMMUNODOT (manual processing)

Product Code	Product Description	Parameters	GMDN code	CE Registration number
		Detection of ... To...		
ANA8D-24	BlueDot ANA ⁸ IgG	IgG <ul style="list-style-type: none"> • Sm • Sm/RNP • SSA/Ro 60kD • SSB • Jo-1 • Scl-70 • PM-Scl 100 • CENP-A/B 	30454	BE-CA02-705-03
ANA10D-24	BlueDot ANA ¹⁰ IgG	IgG <ul style="list-style-type: none"> • Sm • Sm/RNP • SSA/Ro 60kD • SSB • Jo-1 • Scl-70 • PM-Scl 100 • Ku • CENP-A/B • PCNA 	30454	BE-CA02-341-05
ANA12D-24	BlueDot ANA ¹² IgG	IgG <ul style="list-style-type: none"> • Sm • RNP 68 kD/A/C • Sm/RNP • SSA/Ro 60kD • SSB • Jo-1 • Scl-70 • PM-Scl 100 • Ku • CENP-A/B • PCNA • Ribosome P0 	30454	BE-CA02-058-06
ANA12SD-24	BlueDot ANA ¹² Screen IgG	IgG <ul style="list-style-type: none"> • Sm • RNP 68 kD/A/C • Sm/RNP • SSA/Ro 60kD • SSB • Jo-1 • Scl-70 • PM-Scl 100 • Ku • CENP-A/B • PCNA • Mi-2 	30454	BE-CA02-275-06
ANCAGD-24	BlueDot ANCA ^{+GBM} IgG	IgG <ul style="list-style-type: none"> • MPO • PR3 • GBM (Goodpasture) 	54854	BE-CA02-706-03
APSGD-24	BlueDot APS IgG	IgG <ul style="list-style-type: none"> • Cardiolipin/β2-GPI Complex • β2-GPI (isolated protein) 	43075	BE-CA02-322-07
ASCCD-24	BlueDot ASCA IgG+IgA	IgG-IgA <ul style="list-style-type: none"> • S. cerevisiae 	52112	BE-CA02-059-06
BSD-24	BlueDot Milk Intolerance IgG	IgG <ul style="list-style-type: none"> • β-Lactoglobulin • Soya 	30232	BE-CA02-722-03
CHRD-24	BlueDot Chromatin IgG	IgG <ul style="list-style-type: none"> • Nucleosome • dsDNA • Histones 	30454	BE-CA02-291-08
CHR4D-24	BlueDot Chromatin ⁴ IgG	IgG <ul style="list-style-type: none"> • Nucleosome • dsDNA • Histones • DFS-70 	30454	BE-CA01/1-15225-00004-IVD



We Apply Science

D-tekk EC Registration, p. 3 of 9

Product Code	Product Description	Parameters		GMDN code	CE Registration number
		Detection of ...	To...		
CT10D-24	BlueDot Connectivitis ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • Nucleosome • dsDNA • Histones • Sm • Sm/RNP • SSA/Ro 60kD • SSA/Ro 52kD • SSB • Jo-1 • Scl-70 	30454	BE-CA02-292-08
CY6D-24	BlueDot Cytoplasm ⁶ IgG	IgG	<ul style="list-style-type: none"> • M2/nPDC • Jo-1 • PL-7 • PL-12 • SRP-54 • Ribosome P0 	30456	BE-CA02-184-07
ENAD-24	BlueDot ENA ⁶ IgG	IgG	<ul style="list-style-type: none"> • Sm • Sm/RNP • SSA/Ro 60kD • SSB • Jo-1 • Scl-70 	30454	BE-CA02-710-03
ENDA-24	BlueDot Celiac IgA	IgA	<ul style="list-style-type: none"> • Deamidated gliadin • T-transglutaminase 	30480	BE-CA02-711-03
ENDG-24	BlueDot Celiac IgG	IgG	<ul style="list-style-type: none"> • Deamidated gliadin • T-transglutaminase 	30480	BE-CA02-712-03
GAD-24	BlueDot GAD IgG	IgG	<ul style="list-style-type: none"> • GAD 67 kDa • GAD 65 kDa 	54916	BE-CA02-368-13
GR12D-24	BlueDot Granular ¹² IgG	IgG	<ul style="list-style-type: none"> • SSA/Ro 60kD • SSB • Scl-70 • Mi-2 • Ku • TIF1-γ • SAE1/2 • NXP-2 • RNA-Polymerase III • DFS-70 • Sm/RNP • Sm 	30454	BE-CA01/1-15225-00005-IVD
IFPCAD-24	BlueDot Gastritis IgG	IgG	<ul style="list-style-type: none"> • IF (Intrinsic Factor) • PCA (Parietal Cell Antigen) 	30485	BE-CA02-716-03
LISD-24	BlueDot Liver ⁵ IgG	IgG	<ul style="list-style-type: none"> • M2/nPDC • LKM1 • LC1 • SLA • F-Actin 	30456	BE-CA02-719-03
LI7D-24	BlueDot Liver ⁷ IgG	IgG	<ul style="list-style-type: none"> • M2/nPDC • gp210 • sp100 • LKM1 • LC1 • SLA • F-Actin 	30456	BE-CA02-294-08
LI10D-24	BlueDot Liver ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • M2/nPDC • M2/OGDC-E2 • M2/BCOADC-E2 • M2/PDC-E2 • gp210 • sp100 • LKM1 • LC1 • SLA • F-Actin 	30456	BE-CA02-144-11
MI2D-24	BlueDot Mitochondria ² IgG+IgM	IgG/IgM	<ul style="list-style-type: none"> • M2/nPDC • M2 recombinant 	43106	BE-CA02-145-11



We Apply Science

D-tek EC Registration, p. 4 of 9

Product Code	Product Description	Parameters		GMDN code	CE Registration number
		Detection of ...	To...		
MYO7D-24	BlueDot Myositis ⁷ IgG	IgG	<ul style="list-style-type: none"> • Mi-2 • MDA-5 • TIF1-γ • HMGCR • SAE1 • SAE2 • NXP-2 	30462	BE-CA02-017-15
MYO12D-24	BlueDot Myositis ¹² IgG	IgG	<ul style="list-style-type: none"> • Jo-1 • PL-7 • PL-12 • EJ • SRP-54 • Mi-2 • MDA-5 • TIF1-γ • HMGCR • SSA/Ro 52kD • SAE1/2 • NXP-2 	30462	BE-CA02-018-15
MYOS12D-24	BlueDot Myositis ¹² SAE IgG	IgG	<ul style="list-style-type: none"> • Jo-1 • PL-7 • PL-12 • EJ • SRP-54 • Mi-2 • MDA-5 • TIF1-γ • SSA/Ro 52kD • SAE1 • SAE2 • NXP-2 	30462	BE-CA02-260-15
PMS8D-24	BlueDot Polymyositis/Scleroderma ⁸ IgG	IgG	<ul style="list-style-type: none"> • Jo-1 • PL-7 • PL-12 • SRP-54 • Mi-2 • Ku • PM-Scl 100 • Scl-70 	30462	BE-CA02-183-07
PMS12D-24	BlueDot Polymyositis/Scleroderma ¹² IgG	IgG	<ul style="list-style-type: none"> • Jo-1 • PL-7 • PL-12 • EJ • SRP-54 • Mi-2 • MDA-5 • TIF1-γ • Ku • PM-Scl 100 • Scl-70 • SSA/Ro 52kD 	30462	BE-CA02-206-12
RLH12D-24	BlueDot ANA + DFS-70 IgG	IgG	<ul style="list-style-type: none"> • Sm • RNP 68 kD/A/C • Sm/RNP • SSA/Ro 60kD • SSB • Scl-70 • PM-Scl 100 • Ku • CENP-A/B • PCNA • Mi-2 • DFS-70 	30454	BE-CA02-364-13
SCL10D-24	BlueDot Scleroderma ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • Scl-70 • CENP-A • CENP-B • PM-Scl 100 • PM-Scl 75 • Ku • RNA Polymerase III • U1-RNP • Th/To • Fibrillarin 	30462	BE-CA02-019-15



We Apply Science

D-tec EC Registration, p. 5 of 9

Product Code	Product Description	Parameters		GMDN code	CE Registration number
		Detection of ...	To...		
SCL12D-24	BlueDot Scleroderma ¹² IgG	IgG	<ul style="list-style-type: none"> • Scl-70 • CENP-A • CENP-B • PM-Scl 100 • PM-Scl 75 • Ku • RNA Polymerase III • U1-RNP • Th/To • Fibrillarin • NOR-90 • SSA/Ro 52kD 	30462	BE-CA01/1-15225-00001-IVD
SYN10D-24	BlueDot Synthetase ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • Jo-1 • PL-7 • PL-12 • EJ • OJ • KS • ZO • HA • SRP-54 • Ribosome P0 	38442	BE-CA02-020-15

METHODOLOGY: IMMUNODOT (automated processing)

Product Code	Product Description	Parameters		GMDN code	CE Registration number
		Detection of ...	To...		
ANA8DIV-24	BlueDiver Dot ANA ⁸ IgG	IgG	<ul style="list-style-type: none"> • Sm • Sm/RNP • SSA/Ro 60kD • SSB • Jo-1 • Scl-70 • PM-Scl 100 • CENP-A/B 	30454	BE-CA02-041-12
ANA10DIV-24	BlueDiver Dot ANA ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • Sm • Sm/RNP • SSA/Ro 60kD • SSB • Jo-1 • Scl-70 • PM-Scl 100 • Ku • CENP-A/B • PCNA 	30454	BE-CA02-042-12
ANA12DIV-24	BlueDiver Dot ANA ¹² IgG	IgG	<ul style="list-style-type: none"> • Sm • RNP 68 kD/A/C • Sm/RNP • SSA/Ro 60kD • SSB • Jo-1 • Scl-70 • PM-Scl 100 • Ku • CENP-A/B • PCNA • Ribosome P0 	30454	BE-CA02-043-12
ANA12SDIV-24	BlueDiver Dot ANA ¹² Screen IgG	IgG	<ul style="list-style-type: none"> • Sm • RNP 68 kD/A/C • Sm/RNP • SSA/Ro 60kD • SSB • Jo-1 • Scl-70 • PM-Scl 100 • Ku • CENP-A/B • PCNA • Mi-2 	30454	BE-CA02-044-12



We Apply Science

D-tek EC Registration, p. 6 of 9

Product Code	Product Description	Parameters		GMDN code	CE Registration number
		Detection of ...	To...		
ANCAGDIV-24	BlueDiver Dot ANCA ^{+GBM} IgG	IgG	<ul style="list-style-type: none"> MPO PR3 GBM (Goodpasture) 	54854	BE-CA02-046-12
APSGDIV-24	BlueDiver Dot APS IgG	IgG	<ul style="list-style-type: none"> Cardiolipin/β2-GPI Complex β2-GPI (isolated protein) 	43075	BE-CA02-047-12
ASCCDIV-24	BlueDiver Dot ASCA IgG+IgA	IgG-IgA	<ul style="list-style-type: none"> S. cerevisiae 	52112	BE-CA02-048-12
BSDIV-24	BlueDiver Dot Milk Intolerance IgG	IgG	<ul style="list-style-type: none"> β-Lactoglobulin Soya 	30232	BE-CA02-049-12
CHRDIV-24	BlueDiver Dot Chromatin IgG	IgG	<ul style="list-style-type: none"> Nucleosome dsDNA Histones 	30454	BE-CA02-202-12
CHR4DIV-24	BlueDiver Dot Chromatin ⁴ IgG	IgG	<ul style="list-style-type: none"> Nucleosome dsDNA Histones DFS-70 	30454	BE-CA01/1-15225-00006-IVD
CT10DIV-24	BlueDiver Dot Connectivitis ¹⁰ IgG	IgG	<ul style="list-style-type: none"> Nucleosome dsDNA Histones Sm Sm/RNP SSA/Ro 60kD SSA/Ro 52kD SSB Jo-1 Scl-70 	30454	BE-CA02-051-12
CY6DIV-24	BlueDiver Dot Cytoplasm ⁶ IgG	IgG	<ul style="list-style-type: none"> M2/nPDC Jo-1 PL-7 PL-12 SRP-54 Ribosome P0 	30456	BE-CA02-052-12
ENADIV-24	BlueDiver Dot ENA ⁶ IgG	IgG	<ul style="list-style-type: none"> Sm Sm/RNP SSA/Ro 60kD SSB Jo-1 Scl-70 	30454	BE-CA02-053-12
ENDADIV-24	BlueDiver Dot Celiac IgA	IgA	<ul style="list-style-type: none"> Deamidated gliadin t-Transglutaminase 	30480	BE-CA02-054-12
ENDGDIV-24	BlueDiver Dot Celiac IgG	IgG	<ul style="list-style-type: none"> Deamidated gliadin t-Transglutaminase 	30480	BE-CA02-055-12
GADIV-24	BlueDiver Dot GAD IgG	IgG	<ul style="list-style-type: none"> GAD 67 kDa GAD 65 kDa 	54916	BE-CA02-359-13
GR12DIV-24	BlueDiver Dot Granular ¹² IgG	IgG	<ul style="list-style-type: none"> SSA/Ro 60kD SSB Scl-70 Mi-2 Ku TIF1-γ SAE1/2 NXP-2 RNA-Polymerase III DFS-70 Sm/RNP Sm 	30454	BE-CA01/1-15225-00007-IVD
IFPCADIV-24	BlueDiver Dot Gastritis IgG	IgG	<ul style="list-style-type: none"> IF (Intrinsic Factor) PCA (Parietal cell Antigen) 	30485	BE-CA02-058-12
LISDIV-24	BlueDiver Dot Liver ⁵ IgG	IgG	<ul style="list-style-type: none"> M2/nPDC LKM1 LC1 SLA F-Actin 	30456	BE-CA02-060-12
LI7DIV-24	BlueDiver Dot Liver ⁷ IgG	IgG	<ul style="list-style-type: none"> M2/nPDC gp210 sp100 LKM1 LC1 SLA F-Actin 	30456	BE-CA02-061-12



We Apply Science

D-tec EC Registration, p. 7 of 9

Product Code	Product Description	Parameters		GMDN code	CE Registration number
		Detection of ...	To...		
LI10DIV-24	BlueDiver Dot Liver ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • M2/nPDC • M2/OGDC-E2 • M2/BCOADC-E2 • M2/PDC-E2 • gp210 • sp100 • LKM1 • LC1 • SLA • F-Actin 	30456	BE-CA02-062-12
MI2DIV-24	BlueDiver Dot Mitochondria ² IgG+IgM	IgG/IgM	<ul style="list-style-type: none"> • M2/nPDC • M2 recombinant 	43106	BE-CA02-064-12
MYOS12DIV-24	BlueDiver Dot Myositis ¹² SAE IgG	IgG	<ul style="list-style-type: none"> • Jo-1 • PL-7 • PL-12 • EJ • SRP-54 • Mi-2 • MDA-5 • TIF1-γ • SSA/Ro 52kD • SAE1 • SAE2 • NXP-2 	30462	BE-CA02-265-15
PMS8DIV-24	BlueDiver Dot Polymyositis/Scleroderma ⁸ IgG	IgG	<ul style="list-style-type: none"> • Jo-1 • PL-7 • PL-12 • SRP-54 • Mi-2 • Ku • PM-Scl 100 • Scl-70 	30462	BE-CA02-069-12
PMS12DIV-24	BlueDiver Dot Polymyositis/Scleroderma ¹² IgG	IgG	<ul style="list-style-type: none"> • Jo-1 • PL-7 • PL-12 • EJ • SRP-54 • Mi-2 • MDA-5 • TIF1-γ • Ku • PM-Scl 100 • Scl-70 • SSA/Ro 52kD 	30462	BE-CA02-205-12
PRL12DIV-24	BlueDiver Dot PRL ¹² IgG	IgG	<ul style="list-style-type: none"> • Sm • RNP 68 kD/A/C • Sm/RNP • SSA/Ro 60kD • SSA/Ro 52kD • SSB • Jo-1 • Scl-70 • PM-Scl 100 • CENP-A/B • PCNA • DFS-70 	30454	BE-CA02-003-17
RLH12DIV-24	BlueDiver Dot ANA + DFS-70 IgG	IgG	<ul style="list-style-type: none"> • Sm • RNP 68 kD/A/C • Sm/RNP • SSA/Ro 60kD • SSB • Scl-70 • PM-Scl 100 • Ku • CENP-A/B • PCNA • Mi-2 • DFS-70 	30454	BE-CA02-365-13



We Apply Science

D-tec EC Registration, p. 8 of 9

Product Code	Product Description	Parameters		GMDN code	CE Registration number
		Detection of ...	To...		
SCL10DIV-24	BlueDiver Dot Scleroderma ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • Scl-70 • CENP-A • CENP-B • PM-Scl 100 • PM-Scl 75 • Ku • RNA Polymerase III • RNP 68 kD/A/C • Th/To • Fibrillarin 	30462	BE-CA02-014-15
SCL12DIV-24	BlueDiver Dot Scleroderma ¹² IgG	IgG	<ul style="list-style-type: none"> • Scl-70 • CENP-A • CENP-B • PM-Scl 100 • PM-Scl 75 • Ku • RNA Polymerase III • RNP 68 kD/A/C • Th/To • Fibrillarin • NOR-90 • SSA/Ro 52kD 	30462	BE-CA01/1-15225-00002-IVD
SYN10DIV-24	BlueDiver Dot Synthetase ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • Jo-1 • PL-7 • PL-12 • EJ • OJ • KS • ZO • HA • SRP-54 • Ribosome P0 	38442	BE-CA02-011-15

METHODOLOGY: IMMUNODOT (micro-array, automated processing)

Product Code	Product Description	Parameters		GMDN code	CE Registration number
		Detection of ...	To...		
ANA19Q-24	BlueDiver Quantrix ANA ¹⁹ IgG	IgG	<ul style="list-style-type: none"> • Nucleosome • dsDNA • Histones • Sm • RNP 68 kD/A/C • Sm/RNP • SSA/Ro 60kD • SSA/Ro 52kD • SSB • Scl-70 • RNA Polymerase III • Ku • PM-Scl 100 • Mi-2 • Jo-1 • CENP-A/B • PCNA • Ribosome P0 • DFS-70 	30454	BE-CA02-357-13



We Apply Science

D-tekk EC Registration, p. 9 of 9

Product Code	Product Description	Parameters		GMDN code	CE Registration number
		Detection of ...	To...		
ANA25Q-24	BlueDiver Quantrix ANA ²⁵ Screen IgG	IgG	<ul style="list-style-type: none"> • Nucleosome • dsDNA • Histones • Sm • RNP 68 kD/A/C • Sm/RNP • SSA/Ro 60kD • SSA/Ro 52kD • SSB • Scl-70 • Ku • PM-Scl 100 • Mi-2 • Jo-1 • PL-7 • PL-12 • SRP-54 • Ribosome P0 • CENP-A/B • PCNA • sp100 • gp210 • M2 recombinant • M2/nPDC • F-Actin 	30454	BE-CA02-040-12
LI10Q-24	BlueDiver Quantrix Liver ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • M2/nPDC • M2/OGDC-E2 • M2/BCOADC-E2 • M2/PDC-E2 • gp210 • sp100 • LKM1 • LC1 • SLA • f-Actin 	30456	BE-CA02-360-13