


**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.
The Scientific Institute of Public Health, acting as the Belgian Competent Authority for in vitro medical devices (IVD) in the scope of the Directive EC/98/79 has certified the compliance of our products.
-  has a Quality System in place based on ISO 9001 and ISO 13485.
The Quality System has been certified and the Certificate has been issued by Notified Body in April, 2003.
- This Declaration of Conformity is signed below, certifying that the requirements of IVD Directive 98/79/EC have been met and documented.

Date : 3/01/2013

Name : Vigneron Alain



Signature :

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

METHODOLOGY: IMMUNODOT (automated processing)

Product Code	Product Description	Parameters Detection of ...	To...	EDMS code	CE Registration number
ANA8DIV-24	BlueDiver Dot ANA ⁸ IgG	IgG	<ul style="list-style-type: none"> • Sm • Sm/RNP • SSA • 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 • 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 • Sm/RNP • SSA • 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 • Sm/RNP • SSA • SSB • Jo-1 • Scl-70 • PM-Scl 100 • Ku • CENP-A/B • PCNA • Mi-2 	30454	BE-CA02-044-12
ANCADIV-24	BlueDiver Dot ANCA ² IgG	IgG	<ul style="list-style-type: none"> • MPO • PR3 	38442	BE-CA02-045-12
ANCAGDIV-24	BlueDiver Dot ANCA ^{+GBM} IgG	IgG	<ul style="list-style-type: none"> • MPO • PR3 • GBM (Goodpasture) 	38442	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"> • Saccharomyces cerevisiae 	38442	BE-CA02-048-12
BSDIV-24	BlueDiver Dot Milk Intolerance IgG	IgG	<ul style="list-style-type: none"> • β-Lactoglobulin • Soya 	38442	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
CTDIV-24	BlueDiver Dot Connectivitis IgG	IgG	<ul style="list-style-type: none"> • Nucleosome • Histones • Sm • Sm/RNP • SSA • SSB • Jo-1 • Scl-70 	38442	BE-CA02-050-12
CT10DIV-24	BlueDiver Dot Connectivitis ¹⁰ IgG	IgG	<ul style="list-style-type: none"> • Nucleosome • dsDNA • Histones • Sm • Sm/RNP • SSA/Ro60kD • Ro52kD • SSB • Jo-1 • Scl-70 	38442	BE-CA02-051-12
CY6DIV-24	BlueDiver Dot Cytoplasm ⁶ IgG	IgG	<ul style="list-style-type: none"> • M2 (native PDC) • Jo-1 • PL-7 • PL-12 • SRP • 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 • SSB • Jo-1 • Scl-70 	30454	BE-CA02-053-12

Product Code	Product Description	Parameters Detection of ...	To...	EDMS code	CE Registration number
GBDIV-24	BlueDiver Dot GBM IgG	IgG	• GBM (Goodpasture)	43128	BE-CA02-056-12
IFDIV-24	BlueDiver Dot Intrinsic Factor IgG	IgG	• Intrinsic Factor	38442	BE-CA02-057-12
IFPCADIV-24	BlueDiver Dot Gastritis IgG	IgG	• Intrinsic Factor • Parietal cell	30485	BE-CA02-058-12
LI4DIV-24	BlueDiver Dot Liver ⁴ IgG	IgG	• M2 (native PDC) • LKM-1 • LC1 • SLA	38442	BE-CA02-059-12
LISDIV-24	BlueDiver Dot Liver ⁵ IgG	IgG	• M2 (native PDC) • LKM-1 • LC1 • SLA • F-actin	38442	BE-CA02-060-12
LI7DIV-24	BlueDiver Dot Liver ⁷ IgG	IgG	• M2 (native PDC) • gp210 • sp100 • LKM1 • LC1 • SLA • F-actin	38442	BE-CA02-061-12
LI10DIV-24	BlueDiver Dot Liver ¹⁰ IgG	IgG	• M2 (native PDC) • M2/OGDC-E2 • M2/BCOADC-E2 • M2/PDC-E2 • gp210 • sp100 • LKM1 • LC1 • SLA • F-actin	38442	BE-CA02-062-12
LUDIV-24	BlueDiver Dot Lupus IgG	IgG	• Nucleosome • Histones • Sm • Ribosome P0	38442	BE-CA02-063-12
MI2DIV-24	BlueDiver Dot Mitochondria ² IgG+IgM	IgG/IgM	• M2 (native PDC) • M2 recombinant	43106	BE-CA02-064-12
MI4DIV-24	BlueDiver Dot Mitochondria ⁴ IgG+IgM	IgG/IgM	• M2 (native PDC) • M2/OGDC-E2 • M2/BCOADC-E2 • M2/PDC-E2	43106	BE-CA02-065-12
NUDIV-24	BlueDiver Dot Nucleosome IgG	IgG	• Nucleosome	30454	BE-CA02-066-12
NUENADIV-24	BlueDiver Dot ENA ⁺ Nucleosome IgG	IgG	• Nucleosome • Sm • Sm/RNP • SSA • SSB • Jo-1 • Scl-70	30454	BE-CA02-067-12
NUHISDIV-24	BlueDiver Dot Nucleosome/Histones IgG	IgG	• Nucleosome • Histones	30454	BE-CA02-068-12
PMS8DIV-24	BlueDiver Dot Polymyositis/Scleroderma ⁸ IgG	IgG	• Jo-1 • PL-7 • PL-12 • SRP • Mi-2 • Ku • PM-Scl 100 • Scl-70	30462	BE-CA02-069-12
PMS12DIV-24	BlueDiver Dot Polymyositis/Scleroderma ¹² IgG	IgG	• Jo-1 • PL-7 • PL-12 • EJ • SRP • Mi-2 • MDA-5 • TIF1-γ • Ku • PM-Scl 100 • Scl-70 • Ro52 kD	30462	BE-CA02-205-12



We Apply Science



D-tek EC Registration, p. 4 of 4

METHODOLOGY: IMMUNODOT (micro-array, automated processing)

Product Code	Product Description	Parameters Detection of ...	To...	EDMS code	CE Registration number
ANA25Q-24	BlueDiver Quantrix ANA ²⁵ Screen IgG	IgG	<ul style="list-style-type: none"> • Nucleosome • dsDNA • Histones • Sm • RNP (68kD/A/C) • Sm/RNP • SSA/Ro 60kD • Ro 52kD • SSB • Scl-70 • Ku • PM-Scl 100 • Mi-2 • Jo-1 • PL-7 • PL-12 • SRP • Ribosomes • CENP-A/B • PCNA • sp100 • gp210 • M2 recombinant • M2/nPDC • F-actin 	30454	BE-CA02-040-12

Instrument - Software:

Product Code	Product Description	Intended Use	EDMS code	CE Registration number
BLUEDIVER1	BlueDiver Instrument	Semi-automated ImmunoAssay instrument for immunodot kits	220302	BE-CA02-039-12
Dr DOT LIC3	DrDOT Software	Diagnostics & Clinical Interpretation Supporting Software for all the BlueDOT range	38442	BE-CA02-296-08