

Anexa nr. 7
la Documentația standard nr. _____
din “___” _____ 20__

CERERE DE PARTICIPARE

Către IMSP Spitalul Clinic Republican „Timofei Moșneaga”

(denumirea autorității contractante și adresa completă)

Stimați domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, nr ocds-b3wdp1-MD-1656654603070 din 01/07/2022 (ziua/luna/anul), privind aplicarea procedurii pentru atribuirea contractului privind achiziționarea necesităților de reagenți și consumabile de laborator sisteme închise pentru anul 2022 etapa II prin procedura de achiziție licitație deschisă (denumirea contractului de achiziție publică), noi Medist Grup SRL (denumirea/numele ofertantului/candidatului), am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavând obiecții la documentația de atribuire.

Data completării 15.07.2022

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel
(semnătura autorizată)



I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de
drept



**Extras
din Registrul de stat al persoanelor juridice
nr. 100265 din 13.07.2022**

Denumirea completă: **Societatea cu Răspundere Limitată "MEDIST GRUP"**

Denumirea prescurtată: **"MEDIST GRUP" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată**

Numărul de identificare de stat și codul fiscal: **1018600004516**

Data înregistrării de stat: **02.02.2018**

Sediu: **MD-2012, str.Mitropolit Gavriil Bănulescu-Bodoni, 25,ap.33,mun. Chișinău, Republica
Moldova.**

Genurile de activitate:

- 1. Comerț cu ridicata al produselor farmaceutice;**
- 2. Comerț cu ridicata nespecializat;**
- 3. Repararea echipamentelor electronice și optice;**
- 4. Activități de testare și analize tehnice;**
- 5. Comerț cu amănuntul al articolelor medicale și ortopedice, în magazine specializate;**

Capitalul social: **373026 Lei moldovenești**

Administrator(i): **ANGHEL GABRIELA-CRISTINA**

Asociați:

- 1. MEDIST IMAGING & P.O.C. S.R.L. , partea socială 6244 Euro, ce constituie 33%**
- 2. MEDIST LIFE SCIENCE S.R.L., partea socială 6244 Euro, ce constituie 33%**
- 3. MEDIST S.R.L., partea socială 6433 Euro, ce constituie 34%**

Beneficiari efectivi: **Manole Ionel, Vlădescu Carmen, Vlădescu Sebastian-Alexandru, Klumpner
Cătălina**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr.220/2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de 13.07.2022

Specialist coordonator
Victoria Burcovschi
tel. 022-207862



Tip.doc. 1

LEI: Doua Mii Opt Sute Patruzeci si Tre:
i, 30 :

CODUL IBAN:MD57VI022242600000269MDL:
CODUL FISCAL:1018600004516 :

B.C. VictoriaBank S.A. s.26 Chisinau

BENEFICIAR:(R)I.M.S.P. SCR Timofei Mosnea CODUL IBAN:MD32ML000000002251502448:
ga CODUL FISCAL:1003600150783 :

MICB

DESTINATIA PLATII: Garantia pentru oferta, procedu :
ra de achizitie nr.21059296, MTender IDocds-b3wdp1-: NORMAL/URGENT:NO
MD-1656654603070 din 01.07.2022 :

L.S.

DATA PRIMIRII:
DATA EXECUTARII:

SEMNATURILE
EMITENTULUI

SEMNATURA PRESTATORULUI

MOTIVUL REFUZULUI

15:04:26 15 JUL 2022

Semnatura electronica:

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**DECLARAȚIE
privind valabilitatea ofertei**

Către: IMSP Spitalul Clinic Republican „Timofei Moșneaga”

Stimați domni,

Ne angajăm să menținem oferta valabilă, **privind achiziționarea necesităților de reagenți și consumabile de laborator sisteme închise pentru anul 2022 etapa II prin procedura de achiziție licitație deschisă**, pentru o durată de 90 zile, (noua zeci), respectiv până la data de 22/10/2022 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 15.07.2022

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel
(semnătura autorizată)

DECLARAȚIE

Subsemnata Gabriela Anghel, reprezentant împuternicit al MEDIST GRUP S.R.L, cu sediul în mun. Chișinău, str. M.G. Bănulescu-Bodoni 25, Oficiul 33, declar pe propria răspundere că:

- termenul de valabilitate restant (la momentul livrării) va constitui cel puțin de 80% din termenul total al produsului, dar nu mai mic de 12 luni, cu excepția acelor produse ale căror componente nu au termen de valabilitate mai mare de 3-6 luni (materialele de control)

- livrarea produselor la destinatar va avea loc cu respectarea condițiilor de păstrare și transportare.

Data: 15.07.2022

**MEDIST GRUP S.R.L.
DIRECTOR
GABRIELA ANGHEL**



Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc. dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name Part Number (PN)

iQ Calibrator (Pack) 800-3103

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General IVD (non Annex II, non self test)

GMDN Code(s):
42064



Nery Ortiz
Sr. Manager Regulatory Affairs

07 Feb 2019
Date



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level: 1.0
Revision Date: 12/14/2018
Starting Lot #: N/A
Filename: 8003103DEC

Section 1 – Product Identification

Product Name **Part Number (PN)**

iQ Calibrator (Pack) 800-3103

Section 2 – CE Status

☒ First Issue

☐ Revision

/Revision No.1.0

Reason for Revision (if applicable):

N/A-Initial Issue

Section 3 – Standards Applied to Demonstrate Compliance with Directives Below:

EN ISO 13485:2016

EN ISO 14971:2012

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 15223-1:2016

Section 4 – Compliance with Essential Requirements

The product identified in this Technical File Information Sheet has been evaluated in accordance with the Directives and Harmonized Standards identified on the corresponding Declaration of Conformity as attested to below:

Directive	Standards Applied in Full	Compliant	Project Number	Responsible Individual		
				Name	Date	Signature
98/79/EC in vitro Diagnostic Medical Devices	Yes	Yes	9088	Nery Ortiz	07 Feb 2019	



Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

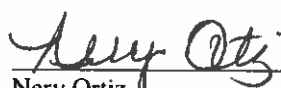
Product Name Part Number (PN)

iQ Control/Focus Set 800-3104

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General IVD (non Annex II, non self test)

GMDN Code(s):
42064



Nery Ortiz
Sr. Manager Regulatory Affairs

07 Feb 2019
Date



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:1.0
Revision Date:12/14/2018
Starting Lot #: N/A
Filename: 8003104DEC

	Document: Declaration of Conformity	Document #: Revision 4.0 GLB-QS-TMP-0029
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Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name Part Number (PN)

Iris Diluent 800-3202

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General

GMDN Code(s):
59058


Nery Ortiz
Sr. Manager Regulatory Affairs

09 Aug 2021
Date



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:2.0
Revision Date:08/09/2021
Starting Lot #: N/A
Filename: 8003202DEC

	Document: Declaration of Conformity	Document #: Revision 4.0 GLB-QS-TMP-0029
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Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

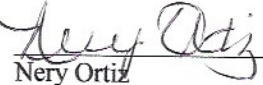
Product Name	Part Number (PN)
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Iris System Cleanser	800-3203
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Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General

GMDN Code(s):
59058


Nery Ortiz
Sr. Manager Regulatory Affairs

09 Aug 2021
Date



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:2.0
Revision Date:08/09/2021
Starting Lot #: N/A
Filename: 8003203DEC



Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

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Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name Part Number (PN)

iQ Lamina 800-3236

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General

GMDN Code(s):

59058


Nery Ortiz

Sr. Manager Regulatory Affairs

07 Feb 2019

Date



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control

Issue Date: 12/14/2018
Revision Level:1.0
Revision Date:12/14/2018
Starting Lot #: N/A
Filename: 8003236DEC



Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name

iChem VELOCITY Urine
Chemistry Strips

Part Number (PN)

800-7204

Conformity Assessment Procedure

Annex III –Self-declared

Classification:

General

GMDN Code(s):

54514

5th March 2021

Marie O'Rourke

Date

Director Quality and Regulatory Affairs



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control

Issue Date: 12/14/2018

Revision Level: 1.2

Revision Date: 03/03/2021

Starting Lot #: 7204500M

Filename: 8007204DEC

	Document: Declaration of Conformity	Document #: Revision 4.0 GLB-QS-TMP-0029
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Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

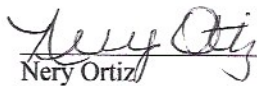
Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Producte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name	Part Number (PN)	Conformity Assessment Procedure
iChem VELOCITY Wash Solution	800-7217	Annex III –Self-declared
		Classification: General
		GMDN Code(s): 59058


Nery Ortiz
Sr. Manager Regulatory Affairs

09 Aug 2021
Date



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:2.0
Revision Date:08/09/2021
Starting Lot #: N/A
Filename: 8007217DEC



Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name

Part Number (PN)

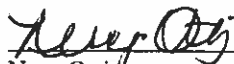
iChemVELOCITY CalChek Kit 800-7703

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General IVD (non Annex II, non self test)

GMDN Code(s):

30219


Nery Ortiz
Sr. Manager Regulatory Affairs

07 Feb 2019
Date



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:1.0
Revision Date:12/14/2018
Starting Lot #: N/A
Filename: 8007703DEC



Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

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Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name Part Number (PN)

IRISpec CA/CB/CC 800-7702

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General IVD (non Annex II, non self test)

GMDN Code(s):
30219

Nery Ortiz
Sr. Manager Regulatory Affairs

07 Feb 2019

Date



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level: 1.0
Revision Date: 12/14/2018
Starting Lot #: N/A
Filename: 8007702DEC



Declaration of Conformity

Beckman Coulter Ireland Inc., hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

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Beckman Coulter Ireland Inc., versichert und erklärt hiermit, daß die im Folgenden aufgeführten Producte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

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Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product	Part Number	Instrument Part Number	GMDN Code
Stand Alone iChemVELOCITY (Int'l)	800-7100	B75503	35918
iChem® VELOCITY™ Back Integrated (Int'l)	800-7103	B75502	35918
iChemVELOCITY, Back Integrated w/o Bridge (Int'l)	800-7162	B75502	35918
iChem® VELOCITY™ StandAlone W/Racks 1-18 (Int'l)	800-7163	B75502	35918
iChem® VELOCITY™ w/ Load/Unload (Int'l)	800-7166	B75502	35918
iChemVELOCITY Computerless System (Int'l)	800-3564	B75502	35918
iChem®VELOCITY™ Dessicant Kit	B79319	N/A	35918
UA WIN10 Kit	C52900	N/A	35918
iQ200 Series Software version 8.0	C50833	N/A	35918

Conformity Assessment Procedure
*Annex III, Self-Declared
CE MARK Affixed*

Classification:
General IVD

Notified Body
N/A

Standard(s) / Norm(en) / Norma(e) / Norme(s) / Norma(s):

EMC: IEC/EN61326-1:2013
IEC/EN61326-2-6:2013

Product Safety: IEC61010-1:2001
IEC61010-2-081:2001
IEC61010-2-101:2002

RoHS: BS EN 50581:2012

Document Control
Issue Date: 05/08/2020
Revision Level: 2.3
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Starting serial #: V04225
RoHS Serial #: V05000
Filename: 2.8.3.10



A handwritten signature in blue ink that reads "Samy Puccio". The signature is written over a horizontal line.

Samy Puccio
Senior Manager, Regulatory Affairs

11 May 2020

Date



Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Clare
Ireland

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland

Holds Certificate Number:

MD 670660

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design and development, manufacture, distribution, installation, service and customer support of clinical chemistry, haematology, heterogenous immunoassay and flow cytometry in vitro diagnostic devices. Manufacture and distribution of infectious disease immunoassays.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-04-12

Latest Revision Date: 2022-04-06

Effective Date: 2021-11-21

Expiry Date: 2024-11-20

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