Anexa nr. 7
la Documentaţia standard nr.____
din "___" _____ 20__

CERERE DE PARTICIPARE

Către IMSP Spitalul Clinic Republican „Timofei Moşneaga"

(denumirea autorităţii contractante şi adresa completă)

Stimaţi 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, neavînd obiecții la documentația de atribuire.

Data completării 15.07.2022

Digitally signed by Anghel Gabriela-Cristina
Date: 2022.07.15 15:12:17 EEST
Reason: MoldSign Signature
Location: Moldova

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

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

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. Chişinău, Republica Moldova.**

Genurile de activitate:

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

Capitalul social: **373026 Lei moldoveneşti**

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**

EB 0415204

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

Specialist coordonator
Victoria Burcovschi
tel. 022-207862

ORDIN DE PLATA NR.329 Tip.doc. 1

DATA EMITERII: 15 iulie 2022

PLATITI:2843-30 LEI: Doua Mii Opt Sute Patruzeci si Trei, 30

PLATITOR: (R)MEDIST GRUP SRL CODUL IBAN:MD57VI022242600000269MDL

CODUL FISCAL:1018600004516

PRESTATORUL PLATITOR

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

BENEFICIAR:(R)I.M.S.P. SCR Timofei Mosnega CODUL IBAN:MD32ML000000002251502448

CODUL FISCAL:1003600150783

PRESTATORUL BENEFICIAR

MICB

DESTINATIA PLATII: Garantia pentru oferta, procedura de achizitie nr.21059296, MTender IDocds-b3wdp1-MD-1656654603070 din 01.07.2022

NORMAL/URGENT:NO

L.S.

CODUL TRANZACTIEI:001

DATA PRIMIRII: _____

DATA EXECUTARII: _____

SEMNATURILE EMITENTULUI

_____

SEMNATURA PRESTATORULUI

«VICTORIABANK» DIRECȚIA OPERAȚIUNI 15. IUL. 2022

MOTIVUL REFUZULUI L.Ș.

15:04:26 15 JUL 2022

Semnatura electronica:

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QRJm8uT5l+J++vEQL+TSo5fxlsLQ0sZX8z0n2A==

DECLARAŢIE
privind valabilitatea ofertei

Către: **IMSP Spitalul Clinic Republican „Timofei Moșneaga”**

Stimaţi domni,

Ne angajăm să menţinem oferta valabilă, **privind achiziţionarea necesităţilor de reagenţi şi consumabile de laborator sisteme închise pentru anul 2022 etapa II prin procedura de achiziţie licitaţie deschisă,** pentru o durată de 90 zile, (noua zeci), respectiv până la data de 22/10/2022 (ziua/luna/anul), şi ea va rămâne obligatorie pentru noi şi poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 15.07.2022

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

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

MEDIST Grup
Soluții pentru sănătate

DECLARAȚIE

Subsemnata Gabriela Anghel, reprezentant împuternicit al MEDIST GRUP S.R.L, cu sediul în mun. Chișinău, str. M.G. Bănulescu-Bodoni 25, Oficul 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

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

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 Produckte 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 listadoes 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:

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

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 Produckte 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 listadoes 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

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 Produckte 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 listadoes 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

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 listadoes 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 System Cleanser	800-3203

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.

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 Produckte 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 listadoes 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 Produckte 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 listadoes 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)
iChem VELOCITY Urine Chemistry Strips	800-7204

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General

GMDN Code(s):
54514

5th March 2021

Marie O'Rourke
Director Quality and Regulatory Affairs

Date

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

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 Produckte 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 listadoes 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)
iChem VELOCITY Wash Solution	800-7217

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: 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 Produckte 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 listadoes 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.

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 Produckte 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 listadoes 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.**

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 Produckte 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 listadoes 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	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

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

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

Classification:
General IVD

Notified Body
N/A

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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
Effective Date: 2021-11-21
Latest Revision Date: 2022-04-06
Expiry Date: 2024-11-20

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