

Anexa nr. 1
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului
și Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale

nr. 2808/1 din 28.08.2023

Solicitantul **FCPC „DataControl” S.R.L.**, cu sediul **mun. Chișinău, str. N. Testemițanu, 17/6**, tel./fax: 022 27 37 12, e-mail: contact@datacontrol.md, solicit
înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri
de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Product: Microscope

Model:

STEREOBLUE

iScope IS.1152-(E)PL(PH)(i)

iScope IS.1153-(E)PL(PH)(i)

iScope IS.1154-(E)PL(PH)(i)

iScope IS.1156-(E)PL(PH)(i)

iScope IS.1158-(E)PL(PH)(i)

IS.3152-(E)PL(F)(i)/LG&LB

IS.3153-(E)PL(F)(i)/LG&LB

IS.3154-(E)PL(F)(i)/LG&LB

IS.3156-(E)PL(F)(i)/LG&LB

IS.3158-(E)PL(F)(i)/LG&LB

IS.1052-PLMi

IS.1053-PLMi

IS.1054-PLMi

IS.1056-PLMi

IS.1058-PLMi

iScope IS.1152-(E)PL(F)(i)/DF(i)

iScope IS.1153-(E)PL(F)(i)/DF(i)

iScope IS.1154-(E)PL(F)(i)/DF(i)

iScope IS.1158-(E)PL(F)(i)/DF(i)

IS.1052-(E)PLPOL(R)(i)

IS.1054-(E)PLPOL(R)(i)

IS.1056-(E)PLPOL(R)(i)

IS.1058-(E)PLPOL(R)(i)

IS.1052-PLAi

IS.1053-PLAi

IS.1054-PLAi

IS.1056-PLAi

IS.1058-PLAi

Se anexează următoarele acte:

1. Declarație de Conformitate CE
2. Actul prin care producătorul își desemnează reprezentantul
3. Declarație pe propria răspundere.

Data **28.08.2023**

Semnătura _____



Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Către
Agenția Medicamentului
și Dispozitivelor Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul **F.C.P.C. "DataControl" S.R.L.**, cu sediul în **mun. Chișinău, str. N. Testemițanu 17/6**, tel./fax: **022 27 37 12**, e-mail: contact@datacontrol.md,

declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Product: Microscope

Model:

STEREOBLUE

iScope IS.1152-(E)PL(PH)(i)

iScope IS.1153-(E)PL(PH)(i)

iScope IS.1154-(E)PL(PH)(i)

iScope IS.1156-(E)PL(PH)(i)

iScope IS.1158-(E)PL(PH)(i)

IS.3152-(E)PL(F)(i)+LG&LB

IS.3153-(E)PL(F)(i)+LG&LB

IS.3154-(E)PL(F)(i)+LG&LB

IS.3156-(E)PL(F)(i)+LG&LB

IS.3158-(E)PL(F)(i)+LG&LB

IS.1052-PLMi

IS.1053-PLMi

IS.1054-PLMi

IS.1056-PLMi

IS.1058-PLMi

iScope IS.1152-(E)PL(F)(i)/DF(i)

iScope IS.1153-(E)PL(F)(i)/DF(i)

iScope IS.1154-(E)PL(F)(i)/DF(i)

iScope IS.1158-(E)PL(F)(i)/DF(i)

IS.1052-(E)PLPOL(R)(i)

IS.1054-(E)PLPOL(R)(i)

IS.1056-(E)PLPOL(R)(i)

IS.1058-(E)PLPOL(R)(i)

IS.1052-PLAi

IS.1053-PLAi

IS.1054-PLAi

IS.1056-PLAi

IS.1058-PLAi

Sunt autentice și corespund realității
Alexandru Grabazei, director

Semnătura

Data: 28.08.2023



DISTRIBUTOR AUTHORIZATIONDate: 30th March, 2023

WHEREAS:

We **Euromex Microscopen BV**, who are official manufacturer, suppliers and wholesalers of Euromex microscopes, digital cameras and accessories, having facilities at Papenkamp 20, 6836 BD Arnhem, The Netherlands

Hereby authorize:

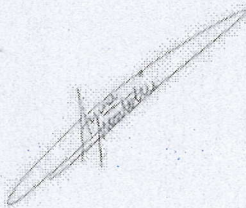
F.C.P.C. "DataControl" S.R.L.,
17/6, N.Testimiteanu street,
MD-2025, Chişinau, Republic of Moldova

As representative in correspondence with the conditions if directive 93/42/EEC, 98/79/EEC to register to the local authorities and 90/385/EEC to deliver, obtain clearance, import, distribute, sell, market, participate in tenders and promote the above-mentioned products to the territory of *Moldova*

We hereby guarantee the quality and performance of the offered products and, provides **DataControl S.R.L** for said products the completion of liabilities deriving contract, in terms of assembly and commissioning services, as well as those of maintenance and technical assistance.

The Authorization has a validity of one year starting from the date of its issuance.

Yours sincerely,



Anna Montoliu
Area Sales Manager
EUROMEX microscopen BV



Euromex Microscopen B.V.
Papenkamp 20 6836 BD
Arnhem - The Netherlands
Tel.: +31 (0)26 323 22 11
info@euromex.com - www.euromex.com



EU Declaration of conformity
EU Konformitätserklärung
Declaración UE de conformidad

EU Conformiteitsverklaring
Déclaration UE de conformité
Dichiarazione UE di conformità

EUROMEX microscopen BV
Papenkamp 20
6836 BD Arnhem, THE NETHERLANDS

Declares under its sole responsibility
that the following products:
Erklärt, unter alleinigen Verantwortung
dass die folgende Produkte:
Declaramos bajo la exclusiva responsabilidad
que los siguientes productos:

Verklaart onder zijn eigen verantwoordelijkheid
dat de volgende producten:
Déclare sous sa seule responsabilité
que les produits suivants:
Dichiara sotto la sua esclusiva responsabilità
che i seguenti prodotti:

iScope IS.1152/3/4/6/8-(E)PL(PH)(i), IS.3152/3/4/6/8-(E)PL(F)(i)+/LG&LB, IS.1052/3/4/6/8-PLMI
iScope IS.1152/3/4/8-(E)PL(F)(i)/DF(i), IS.1052/2/4/6/8-(E)PLPOL(R)(i), IS.1052/3/4/6/8-PLAI
microscopes / microscopen / Mikroskop / microscopes / microscopios / microscopi

are in conformity with the provisions of
the following European Directives:
den folgenden Bestimmungen der
europäischen Richtlinien entsprechen:
cumplen con las siguientes disposiciones
de las directivas europeas:

in overeenstemming zijn met de bepalingen
van de volgende Europese richtlijnen:
sont en conformité avec les
directives Européenne suivantes:
sono conformi alle seguenti
disposizioni delle direttive europee:

EMC-directive	2014-30-EU
Low voltage directive	2014-35-EU
RoHS-directive II	2011-65-EU
RoHS-directive III	2015-863-EU

(Electromagnetic compatibility)
(Electrical equipment))
(Restriction of Hazardous substances)
(Restriction of Hazardous substances)

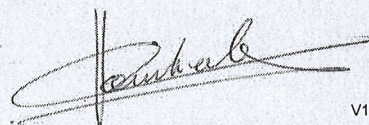
assessed using following applicable
European Harmonised Standards:
nach folgenden geltenden europäischen
harmonisierten Normen bewertet:
evaluados utilizando los siguientes
estándares europeos armonizados:

beoordeeld aan de hand van de toepasselijke
Europese geharmoniseerde normen:
évalués selon les normes harmonisées
européennes adoptées suivantes:
valutato utilizzando i seguenti standard
armonizzati europei applicabili

EN 61326-1	Electrical equipment for measurement, control and laboratory use - EMC requirements
EN 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use (Low Voltage)
IEC 62321-3/4/5/6/7/8	Assessment of electrical and electronic products with respect to the restriction of hazardous substances (ROHS)
EN 62471	Photobiological safety of lamps and lamp systems and LEDs

The product herewith complies with the requirements of the European directives and harmonized standards and carries the CE-marking accordingly

Ing. Vanherle R. – CE Compliance manager
Arnhem 01.11.2021



V13139-2





EU Declaration of conformity
EU Konformitätserklärung
Declaración UE de conformidad

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Dichiarazione UE di conformità

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dat de volgende producten:
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Dichiara sotto la sua esclusiva responsabilità
che i seguenti prodotti:

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microscopes / microscopen / Mikroskop / microscopes / microscopios / microscopi

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europäischen Richtlinien entsprechen:
cumplen con las siguientes disposiciones
de las directivas europeas:

in overeenstemming zijn met de bepalingen
van de volgende Europese richtlijnen:
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EMC-directive	2014-30-EU
Low voltage directive	2014-35-EU
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(electromagnetic compatibility)
(electrical equipment))
(Restriction of Hazardous substances)

assessed using following applicable
European Harmonised Standards:
nach folgenden geltenden europäischen
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evaluados utilizando los siguientes
estándares europeos armonizados:

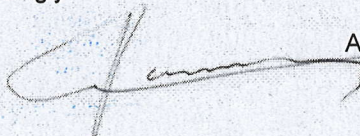
beoordeeld aan de hand van de toepasselijke
Europese geharmoniseerde normen:
évalués selon les normes harmonisées
européennes adoptées suivantes:
valutato utilizzando i seguenti standard
armonizzati europei applicabili

EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements
EN 61010-1:2010	Safety requirements for electrical equipment for measurement, control, and laboratory use (Low Voltage)
IEC 62321-3	Assessment of electrical and electronic products with respect to the restriction of hazardous substances (ROHS-II)



The product herewith complies with the requirements of the European directives and harmonized standards and carries the -marking accordingly

Vanherle R.
Product Compliance Manager



Arnhem 20.01.2019