



DoC/IMMUNOLOGY

Révision : 2

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DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

Validity declaration of conformity from date / Date de déclaration de conformité :

Place / Lieu d'émission : Marcy l'Etoile

Date of the issue of the declaration of conformity /
Date d'application de la déclaration de conformité : 2022 JAN 14

Name - Title / Nom - Fonction : Manuela Kaul – VP Global Clinical & Regulatory Affairs

Signature :

DocuSigned by:

Signer Name: Manuela KAUL
Signing Reason: I approve this document
Signing Time: 1/14/2022 | 8:44:05 AM CET
9CF4CB25EF8C4C80B1A742856CE59B23

Product identification / Identification du produit :

Name – Product code number / Nom – Référence :

Global Eu DoC IMMUNOLOGY – REV2.xls”

Refer to the attached list “Attachment 1 to

Identification of the person who has the power of attorney to bind the manufacturer / Nom et qualité de la personne engageant la responsabilité du fabricant :

Name / Nom : Manuela KAUL

Title / Fonction : VP Global Clinical & Regulatory Affairs

Identification of the legal entity / Identification de l'entité légale :

Manufacturer / Fabricant :

Name / Nom : BIOMERIEUX SA

Address / Adresse : 376 Chemin de l'Orme – 69280 Marcy l'Etoile -
France

« We, the manufacturer declare that the above mentioned products comply with the Directives and their relevant implementations into all national laws of the member states into which we place the products » / « Nous, fabricant, déclarons que les produits mentionnés ci-dessus satisfont aux Directives et leurs transpositions en droit national dans les Etats Membres dans lesquels les produits sont mis sur le marché. »



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DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE

Conformity assessment procedure used to demonstrate compliance / Procédure d'évaluation de conformité choisie :

Annex / Annexe (s) :
IMMUNOLOGY – REV2.xls”

Refer to the attached list “Attachment 1 to Global Eu DoC

Directive (s) : 98/79/CE

Device classification / Classification du dispositif :

Refer to the attached list

“Attachment 1 to Global Eu DoC IMMUNOLOGY – REV2.xls”

Directive 98/79/CE : List(e) A, Annex(e) II List(e) B, Annex(e) II Other / Autre Self-testing / Autotest

Identification of certificate(s) and Notified Body which issued it (them) / Identification du (des) certificat(s) et Organisme Notifié :

Name of Notified Body / Nom de l'Organisme notifié :

GMED -  0459

Certificate(s) number / Numéro d'identification du(des) certificat(s) :
“Attachment 1 to Global Eu DoC IMMUNOLOGY – REV2.xls”

Refer to the attached list

Attachment 1 to Global Eu DoC IMMUNOLOGY rev2

					Certificate delivered by the Notified Body: LNE-G-MED - CE 0459		
Product code	Product name	Device classification	Conformity assessment procedure	Manufacturing site name	QA Certificate N°	Design examination Certificate N°	EC type examination Certificate N°
IMMUNOASSAYS - VIDAS (PC) Instrument, Accessories, Software							
410417	VIDAS®	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
99735	VIDAS analyzer	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
93567	VIDAS® Lens Cleaner	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
423447	VIDAS PC v4.9 Windows 10 update	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
413453	VIDAS® PC Update Kit V4.7.0	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
415364	VIDAS® PC SOFTWARE RP5800 V4.7.1 (BCI Link 4.0.0.22)	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
417894	VIDAS® PC V4.7.1 (BCI Link 4.0.0.22) UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
IMMUNOASSAYS - miniVIDAS Instrument, Accessories, Software							
410416	mini VIDAS®	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
99737	mini VIDAS analyzer	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
93567	VIDAS® Lens Cleaner	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
413452	miniVIDAS® Update Kit1 V5.6.0	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
414200	miniVIDAS® Update Kit2 V5.6.0	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423117	MINI VIDAS FLASH CARD V5.6.1	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
93493	mini VIDAS UPDATE KIT V5.2.0	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
93605	mini VIDAS® V5.3.0 Software Kit	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
IMMUNOASSAYS - VIDAS 3 Instrument, Accessories, Software							
412590	VIDAS® 3	except Annex II and self-testing devices	Annex III (section 6 excluded)	10	N/A	N/A	N/A
412500	VIDAS® 3 Assay dilution cup	except Annex II and self-testing devices	Annex III (section 6 excluded)	20	N/A	N/A	N/A
412501	VIDAS® 3 Sample tips	except Annex II and self-testing devices	Annex III (section 6 excluded)	19	N/A	N/A	N/A
416460	VIDAS® 3 RP5800 DVD MASTER V1.1.2 (BCI Link 4.0.0.22)	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
419001	VIDAS® 3 V.1.1.4 UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
419002	VIDAS® 3 RP5800 DVD MASTER V1.1.4	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
421731	VIDAS® 3 V.1.2 UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A

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422105	VIDAS® 3 1.2.1 UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423135	VIDAS 3 V1.3 DVD SW UPDATE	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423146	VIDAS 3 V1.2.2 UPDATE KIT	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423630	VIDAS V3 1.3.2	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
423694	VIDAS 3 V1.4 Software	except Annex II and self-testing devices	Annex III (section 6 excluded)	3	N/A	N/A	N/A
IMMUNOASSAYS - VIDAS Reagents							
30115	VIDAS® Protein C	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30117	VIDAS® HIV P24 II	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9121	N/A
30118	VIDAS® C. difficile Toxin A & B	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30125	VIDAS® C. difficile GDH	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30192	VIDAS® H. pylori IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30202	VIDAS® Toxo IgM	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9111
30202-30	VIDAS® Toxo IgM	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9111
30204	VIDAS® CMV IgG	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9126
30205	VIDAS® CMV IgM	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9127
30210	VIDAS® TOXO IgG II	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
30211	VIDAS® TOXO Compétition	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	8329
30214	VIDAS® RUB IgM	Annex II-B	An.V + VII (sec. 5 excluded)	1	9136	N/A	9110
30217	VIDAS® Varicella-Zoster IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30218	VIDAS® Mumps IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30219	VIDAS® Measles IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30221	VIDAS® RUB IgG II	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
30222	VIDAS® TOXO IgG AVIDITY	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
30235	VIDAS® EBV EBNA IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A

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30236	VIDAS® EBV VCA/EA IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30237	VIDAS® EBV VCA IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30305	VIDAS® HBe/Anti-HBe	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9138	N/A
30307	VIDAS® HAV IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30308	VIDAS® Anti-HCV	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	23068	N/A
30312	VIDAS® Anti-HAV Total	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30314	VIDAS® Anti-HBc Total II	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	8470	N/A
30315	VIDAS® HBs Ag Ultra	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	8325	N/A
30317	VIDAS® HBs Ag Ultra Confirmation	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9120	
30318	VIDAS® Anti-HBs Total II	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	26813	N/A
30319	VIDAS® Lyme IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30320	VIDAS® Lyme IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30400	VIDAS® TSH	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30402	VIDAS® FT3	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30403	VIDAS® T3	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30404	VIDAS® T4	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30405	VIDAS® HCG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30406	VIDAS® LH	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30407	VIDAS® FSH	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30409	VIDAS® Progesterone	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30410	VIDAS® Prolactin	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30411	VIDAS® Ferritin	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30413	VIDAS® AFP	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30419	VIDAS® TOTAL IgE	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30420	VIDAS® β2 Microglobulin	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A

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30421	VIDAS® CK-MB	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30426	VIDAS® CA 125 II™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30427	VIDAS® CA 19-9™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30428	VIDAS® TPSA	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
30429	VIDAS® CA 15-3®	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30431	VIDAS® Estradiol II	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30436	VIDAS® vWF	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30439	VIDAS® HBc IgM II	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9119	N/A
30440	VIDAS® FPSA	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
30441	VIDAS® TSH3	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30443	VIDAS® HIV DUO Ultra	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9123	N/A
30444	VIDAS® HIV P24 II Confirmation	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9122	N/A
30446	VIDAS® Myoglobin	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30447	VIDAS® HIV DUO Quick	Annex II-A	An.IV (sec.4 and 6 included)	1	8330	9124	N/A
30448	VIDAS® TROPONIN I Ultra	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30450	VIDAS® B.R.A.H.M.S PCT™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30450-30	VIDAS® B.R.A.H.M.S PCT™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30450-86	VIDAS® B.R.A.H.M.S PCT™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30451	VIDAS® Cortisol S	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30451-30	VIDAS® Cortisol S	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30453	VIDAS® CEA (S)	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30455	VIDAS® D-Dimer Exclusion II™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30455-02	VIDAS® D-Dimer Exclusion II™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
30455-30	VIDAS® D-Dimer Exclusion II™	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A

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Product code	Product name	Device classification	Conformity assessment procedure	Manufacturing site name	QA Certificate N°	Design examination Certificate N°	EC examination type Certificate N°
30458	VIDAS® NT-proBNP2	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
30458-30	VIDAS® NT-proBNP2	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
30459	VIDAS® FT4	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
30461	VIDAS® Anti-TPO	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
30462	VIDAS® Anti-Tg	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
30463	VIDAS® 25 OH Vitamin D TOTAL	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
30603	VIDAS® Digoxin	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
30706	Quality Control VIDAS® (QCV)	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
413557	VIDAS® CMV IgG Avidity II	Annex II-B	An.IV (sec.4 and 6 excluded)	1	8330	N/A	N/A
414320	VIDAS® Testosterone II	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
415386	VIDAS® High sensitive Troponin I	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
415386-30	VIDAS® High sensitive Troponin I	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
417011	VIDAS® Anti-Müllerian Hormone	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
418115	VIDAS® Anti-HEV IgM	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
418116	VIDAS® Anti-HEV IgG	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
422010	VIDAS® PTH (1-84)	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
423833	VIDAS® SARS-COV-2 IgM	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
423834	VIDAS® SARS-COV-2 IgG	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
421172	VIDAS® NEPHROCHECK®	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
421172-03	VIDAS® NEPHROCHECK®	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
423111	VIDAS® TB-IGRA	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
423077	VIDAS® DENGUE NS1 Ag	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A
423078	VIDAS® Anti-DENGUE IgM	except Annex II and self-testing devices	Annex III (section excluded) 6	1	N/A	N/A	N/A

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423079	VIDAS® Anti-DENGUE IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
423833	VIDAS® SARS-COV-2 IgM	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
423834	VIDAS® SARS-COV-2 IgG	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
424114	VIDAS® SARS-COV-2 IgG II	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
424069	VIDAS IFNg QC Panel	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
IMMUNOSEROLOGY - Reagents							
66581	SERUM FREE	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
72331	ASD-Kit	except Annex II and self-testing devices	Annex III (section 6 excluded)	1	N/A	N/A	N/A
75361	Toxo-ISAGA	Annex II-B	An.V + VII (sec. 5 excluded)	1	9137	N/A	9125
79322	Toxo-ISAGA IgA	Annex II-B	An.V + VII (sec. 5 excluded)	1	9137	N/A	9100

Production Site code	Name	Address	Country
1	BIOMERIEUX S.A.	376 Chemin de l'Orme - 69280 Marcy l'Etoile	France
2	BIOMERIEUX S.A.	5 rue des Aqueducs - 69290 CRAPONNE	France
3	BIOMERIEUX S.A.	3 route de Port Michaud - 38390 LA BALME LES GROTTES	France
4	BIOMERIEUX S.A.	Centre Christophe Mérieux - 5 rue des Berges - 38024 GRENOBLE CEDEX 01	France
5	BIOMERIEUX S.A.	138 rue Louis Pasteur, Parc Technologique Delta Sud - 09340 VERNIOLLE	France
6	BIOMERIEUX S.A.	Route de Dol - 35270 COMBOURG	France
7	bioMérieux, Inc.	100 Rodolphe Street, Durham, North Carolina 27712	USA
8	BioMérieux, Inc.	595 Anglum Road, Hazelwood, Missouri 63042	USA
9	BIOMERIEUX ESPANA S.A.	C/Isaac Newton n° 6 - Parque Tecnológico de Madrid Tres Cantos 28760	Spain
10	BIOMERIEUX Italia S.p.A.	Via di Campigliano, 58 - Ponte a Ema, 50012 Bagno a Ripoli (Firenze)	Italy
11	bioMerieux (Shanghai) Compagny Limite	No.4633, Pusan Road, Pudong District, SHANGHAI, CHINA, 201315	China
12	ELITechGroup Inc.	370 West 1700 South - Logan, Utah 84321	USA
13	RAL DIAGNOSTICS	Site Montesquieu, Bordeaux Technopolis - 33650 Martillac	France
14	Orion Diagnostica Oy	Koivu-Mankkaan tie 6 B, P.O. Box 83, Espoo, FI-02101	Finland
15	Revere Plastic Systems, LLC	1452 Rowe Parkway, Poplar Bluff, Missouri, 69301	USA
16	Gerresheimer	650 Highway 74 South - Peachtree City, GA 30269	USA
17	MEDISIZE CZ s.r.o	Tovami 560 274 15 Trhové Sviny	Czech Republic
18	Kratos Analytical Ltd	Wharf Side, Trafford Wharf Road, Manchester, M17 1GP	United-Kingdom
19	Eppendorf AG	Barkhausenweg 1, 22339 Hamburg - Germany	Germany
20	PLASTIBELL PHARM II	150 Z.I. La Plaine, B.P. 16, 01580 Izernore - France	France
21	Sanmina-SCI AB	Svedjevägen 12, SE-891 23 Örnköldsvik	Sweden
22	Hach Company	100 Dayton Avenue, Ames, IA 50010	USA
23	Qnostics Ltd	2 Block 4.01, Kelvin Campus, West Scotland Science Park, Glasgow G20 0SP	United-Kingdom
24	STRATEC Consumables GmbH	Sonystrabe 20, 5081 Anif	Austria
25	REMEL	12076 Sante Fe Drive, Lenexa, KS 66212 USA	United States