

认证证书

标准 ISO 9001:2015

证书登记号码 01 100 1632686

证书持有者: 瑞华塑业(常州)有限公司
统一社会信用代码: 91320404666358586K
注册地址: 中国江苏省常州市钟楼区邹区镇林场村
邮编: 213141
经营地址: 中国江苏省常州市钟楼区邹区镇常金东路 45 号
邮编: 213141

认证范围: 实验室及医疗用塑料耗材的生产

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期: 证书有效期从 2019-04-21 至 2022-04-20。
此证书须经过符合要求的监督审核保持有效。
初次发证始于 2016 年

本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2019-04-08



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com



Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1632686**

Certificate Holder: **Biologix Plastics (Changzhou) Co., Ltd.**
Unified Social Credit Code: 91320404666358586K
Registration Address: Linchang Village,
Zouqu Town, Zhonglou District, Changzhou City,
Jiangsu Province 213141, P. R. China
Operation Address: No. 45, East Changjin Road,
Zouqu Town, Zhonglou District, Changzhou City,
Jiangsu Province 213141, P. R. China

Scope: Manufacturing of Plastic Consumables for Laboratory
and Medical Treatment

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2019-04-21 until 2022-04-20.
It remains valid subject to satisfactory surveillance audits.
First certification 2016

This certificate information can be searched on CNCA official
website <http://www.cnca.gov.cn>

2019-04-08



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Compliance Report

Applicant: Biologix Plastics (Changzhou) Co., Ltd.
Address: LinChang Village, Zouqu Town, Zhonglou District, Changzhou City, Jiangsu Province 213141, P.R. China.

Product: See annex for details
Type: See annex for details

Product Classification: Others

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex II & III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive.

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 03069
Initial Issue Date: 31 Jan 2021

A handwritten signature in blue ink that reads 'Tony Chen'.

General Manager (Signature)

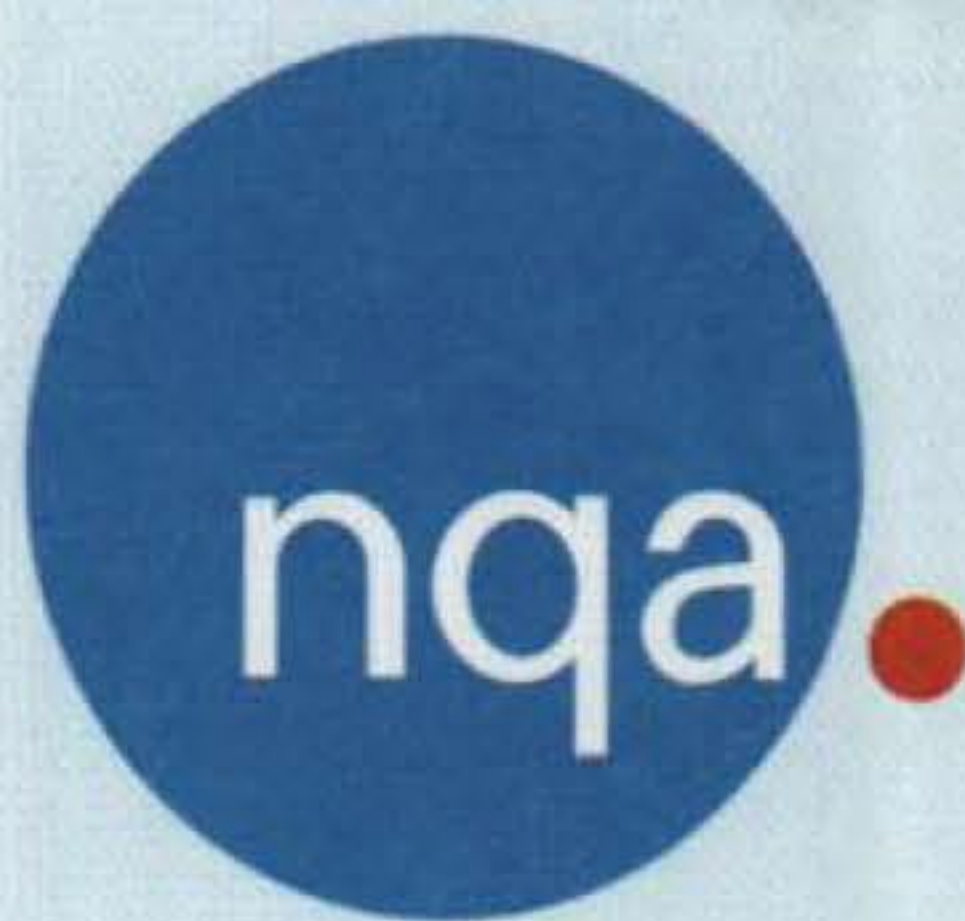


Annex to Report (No. 03069)

Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
Centrifuge Tubes	10-9151, 10-9152, 10-9501, 10-9502, 10-9815, 10-9850, 10-0151, 10-0152, 10-0501, 10-0502, 10-0815, 10-0850, 10-0122, 10-0123 10-9052-RO, 10-9082-RO, 10-0082-Y, 10-0101-Y, 10-9502E
Microcentrifuge Tubes	80-1500, 80-1501, 80-1502, 80-1503, 80-0015, 80-0500, 80-0020
Test Tubes and Caps	12-1275, 12-2275, 12-1300, 12-1299, 12-1399
Screw Cap Microtubes and Caps	81-0053, 81-0054, 81-0153, 81-0154, 81-0203, 81-0204, 81-0000, 81-0001, 81-0002, 81-0003, 81-0004, 81-0005, 10-0101, 10-0082, 10-0052, 10-0000, 82-7215, 82-7216, 82-7217, 82-7218, 82-7219, 82-7115, 82-7116, 82-7117, 82-7118, 82-7119, 82-7054, 82-7055, 82-7056, 82-7057, 82-7058, 82-7059, 82-7060, 82-7061, 82-7153, 82-7162, 82-7163, 82-7164, 82-7165, 82-7166, 82-7167, 82-7168, 82-7154, 82-7155, 82-7156, 82-7157, 82-7158, 82-7159, 82-7160, 82-7161, 82-7204, 82-7205, 82-7206, 82-7207, 82-7208, 82-7209, 82-7210, 82-7211, 81-0055, 81-0056, 81-0006, 81-0204S, 81-0000S
Cryogenic Vials	81-7053, 81-7054, 81-7153, 81-7154, 81-7203, 81-7204, 81-8053, 81-8054, 81-8153, 81-8154, 81-8203, 81-8204, 81-7055, 81-7056, 81-7205, 88-6210, 88-6211, 88-6212, 88-6213, 88-6214, 88-6215, 88-6216, 88-6217, 88-6200, 88-6201, 88-6202, 88-6203, 88-6204, 88-6205, 88-6206, 88-6207, 88-6500, 88-6501, 88-6502, 88-6503, 88-6504, 88-6505, 88-6506, 88-6507, 88-6000, 88-6001, 88-6002, 88-6003, 88-6004, 88-6005, 88-6006, 88-6007, 88-3210, 88-3211, 88-3212, 88-3213, 88-3214, 88-3215, 88-3216, 88-3217, 88-3200, 88-3201, 88-3202, 88-3203, 88-3204, 88-3205, 88-3206, 88-3207, 88-3500, 88-3501, 88-3502, 88-3503, 88-3504, 88-3505, 88-3506, 88-3507, 81-7204-DB 81-7154-DB 81-7204-GB
PCR Tubes & Plates	60-0082, 60-0182, 60-0282, 60-0382, 60-0482, 60-0002, 60-0102, 60-0202, 60-0302, 60-0402, 60-0008, 60-0108, 60-0208, 60-0308, 60-0408, 60-0088, 60-0188, 60-0288, 60-0388, 60-0488, 60-0056, 60-0156, 60-0256, 60-0356, 60-0456

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Annex to Report (No. 03069)

Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
Pipet Tips	20-0010, 20-0200, 20-1000, 21-0010, 21-0200, 21-1000, 20-1250, 21-1250, 20-1251
Transfer Pipets	30-0135, 30-0135A1, 30-0135B20, 30-0138,30-0138A1, 30-0138B20, 30-0238A1
Tri-Cornered Beakers	93-0050, 93-0100, 93-0250, 93-0400, 93-0800, 93-1000
Solution Basins	25-0052, 25-0051, 25-1202, 25-1025, 25-1100, 25-1202
Microtube Racks	90-8009, 90-1550, 90-5025
Plastic Cryogenic Storage Boxes	90-9009, 90-9250, 90-9081, 90-9100, 90-9025, 90-9210, 90-9200, 90-9381
Cardboard Freezer Boxes	90-1281, 90-1200, 90-1381, 90-1300, 90-2281, 90-2200, 90-2381, 90-2300, 90-6281, 90-6200, 90-1536, 90-5016, 90-5281, 90-5200, 90-6100, 90-1100, 90-1100, 90-8281, 90-8200, 90-8100, 90-8381
Cell Scrapers & Lifters	70-1180, 70-1250, 70-2180
Cell Strainers	15-1040, 15-1070, 15-1100
Slide Storage Boxes	41-5025, 41-5100, 41-6025, 41-6100, 7101, 7105
Slide Mailers	41-4001, 41-4002, 41-4020
Drosophila Vials	51-0500, 51-0501, 51-0800, 51-0801
Drosophila Bottles	51-17720, 51-17721
Petri Dishes	66-1501, 66-1560, 66-1515, 66-1701
Inoculating Loops & Needles	65-0001, 65-0010, 65-0002
Product Name	Type
Cell Spreaders	65-1001,65-1010
Stainless Steel Freezer Racks	99-1224, 99-1220, 99-1216, 99-2224, 99-2220, 99-2216, 99-2215, 99-2212, 99-5220, 99-5216, 99-5215, 99-5212, 99-1132, 99-1128, 99-1124, 99-2132, 99-2128, 99-2124, 99-2120, 99-2121, 99-2118, 99-6207, 99-6209, 99-6210, 99-6212, 99-6213, 99-7220, 99-7224, 99-7216, 99-7132, 99-7128, 99-7124, 99-2230, 99-6206, 99-6208, 99-6211, 96-2118, 96-2121, 96-2120, 96-2124, 96-2128, 96-2132, 96-2212, 96-2215, 96-2216, 96-2220, 96-2224, 96-2230, 96-6206, 96-6207, 96-6208, 96-6209, 96-6210, 96-6211, 96-6212, 96-6213, 96-1216, 96-1220, 96-1224, 96-1124, 96-1128, 96-1132, 96-7216, 96-7220, 96-7224, 96-7124, 96-7128, 96-7132

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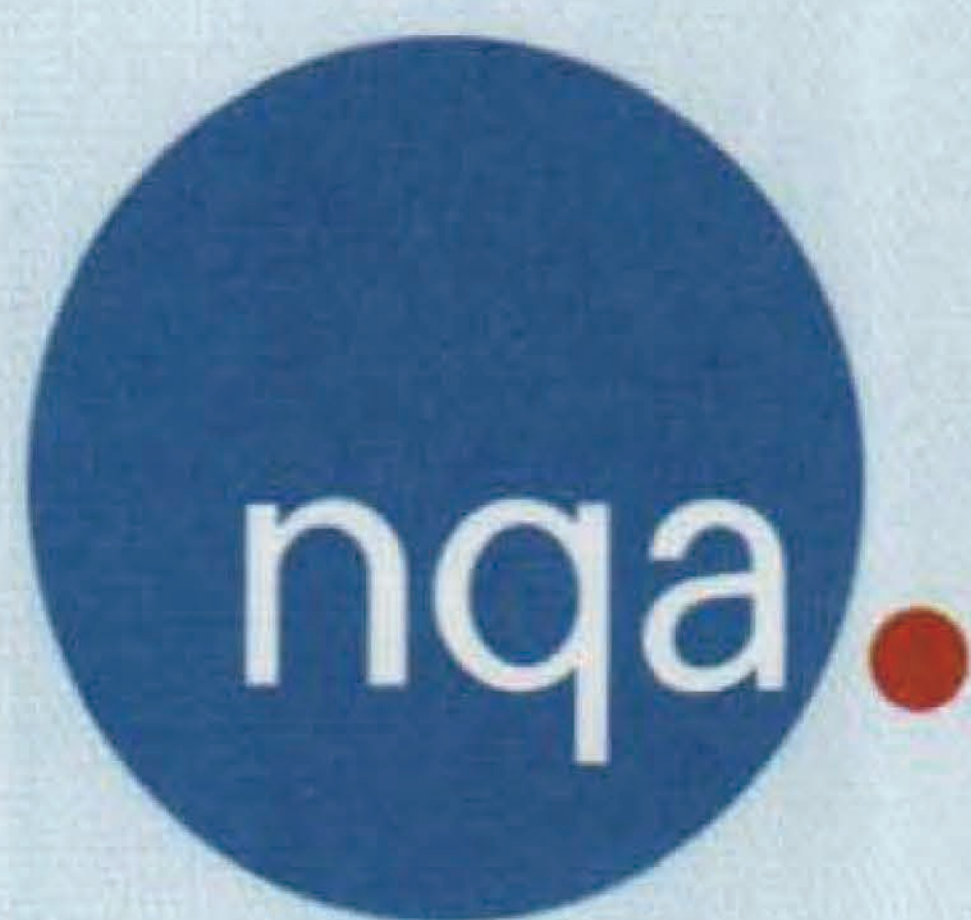


Annex to Report (No. 03069)

Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
CryoKING Cryogenic Vials	88-0050,88-0051,88-0052,88-0053,88-0054,88-0055, 88-0100, 88-0101, 88-0102, 88-0103, 88-0104, 88-0105, 88-0150, 88-0151, 88-0152, 88-0153, 88-0154, 88-0155, 88-1050, 88-1051, 88-1052,88-1053, 88-1054, 88-1055, 88-1100, 88-1101, 88-1102, 88-1103, 88-1104, 88-1105, 88-1150, 88-1151, 88-1152, 88-1153, 88-1154, 88-1155, 88-0056, 88-0057, 88-0106, 88-0107, 88-0156, 88-0157, 88-0200, 88-0201, 88-0202, 88-0203, 8-0204, 88-0205, 88-0206, 88-0207, 88-0210, 88-0211, 88-0212, 88-0213, 88-0214, 88-0215, 88-0216, 88-0217, 88-0500, 88-0501, 88-0502, 88-0503, 88-0504, 88-0505, 88-0506, 88-0507, 88-1056, 88-1057, 88-1106, 88-1107, 88-1156, 88-1157, 88-1200, 88-1201, 88-1202, 88-1203, 88-1204, 88-1205, 88-1206, 88-1207, 88-1210, 88-1211, 88-1212, 88-1213, 88-1214, 88-1215, 88-1216, 88-1217, 88-1500, 88-1501, 88-1502, 88-1503, 88-1504, 88-1505, 88-1506, 88-1507, 88-6050, 88-6051, 88-6052, 88-6053, 88-6054, 88-6055, 88-6056, 88-6057, 88-6100, 88-6101, 88-6102, 88-6103, 88-6104, 88-6105, 88-6106, 88-6107, 88-6150, 88-6151, 88-6152, 88-6153, 88-6154, 88-6155, 88-6156, 88-6157, 88-7200, 88-7201, 88-7202, 88-7203, 88-7204, 88-7205, 88-7206, 88-7207, 88-7210, 88-7211, 88-7212, 88-7213, 88-7214, 88-7215, 88-7216, 88-7217, 88-7500, 88-7501, 88-7502, 88-7503, 88-7504, 88-7505, 88-7506, 88-7507, 88-9050, 88-9051, 88-9052,88-9053, 88-9054,88-9055, 88-9056, 88-9057, 88-9100, 88-9101, 88-9102, 88-9103, 88-9104, 88-9105, 88-9106, 88-9107, 88-9150, 88-9151, 88-9152, 88-9153, 88-9154, 88-9155, 88-9156, 88-9157, 88-9200, 88-9201, 88-9202, 88-9203, 88-9204, 88-9205, 88-9206, 88-9207, 88-9210, 88-9211, 88-9212, 88-9213, 88-9214, 88-9215, 88-9216, 88-9217, 88-9500, 88-9501, 88-9502, 88-9503, 88-9504, 88-9505, 88-9506, 88-9507, 88-4030, 88-4031, 88-4032, 88-4033, 88-4034, 88-4035, 88-4036, 88-4037, 88-4050, 88-4051, 88-4052, 88-4053, 88-4054, 88-4055, 88-4056, 88-4057, 88-4080, 88-4081, 88-4082, 88-4083, 88-4084, 88-4085, 88-4086, 88-4087, 88-4100, 88-4101, 88-4102, 88-4103, 88-4104, 88-4105, 88-4106, 88-4107, 88-4210, 88-4211, 88-4212, 88-4213, 88-4214, 88-4215, 88-4216, 88-4217, 88-4200, 88-4201, 88-4202, 88-4203, 88-4204, 88-4205, 88-4206, 88-4207, 88-4500, 88-4501, 88-4502, 88-4503, 88-4504, 88-4505, 88-4506, 88-4507

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Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
PC Cryogenic Boxes	98-0113, 98-0213, 98-0313, 98-0200, 98-0213, 98-4217, 98-4317, 98-4417, 98-4117, 98-4127, 98-4227
CryoKING Combo	89-3050, 89-3051, 89-3052, 89-3053, 89-3054, 89-3055, 89-3100, 89-3101, 89-3102, 89-3103, 89-3104, 89-3105, 89-3150, 89-3151, 89-3152, 89-3153, 89-3154, 89-3155, 89-3056, 89-3057, 89-3106, 89-3107, 89-3156, 89-3157, 89-3200, 89-3201, 89-3202, 89-3203, 89-3204, 89-3205, 89-3206, 89-3207, 89-3210, 89-3211, 89-3212, 89-3213, 89-3214, 89-3215, 89-3216, 89-3217, 89-3500, 89-3501, 89-3502, 89-3503, 89-3504, 89-3505, 89-3506, 89-3507, 89-4820, 89-4821, 89-4822, 89-4823, 89-4824, 89-4825, 89-4826, 89-4827, 89-4850, 89-4851, 89-4852, 89-4853, 89-4854, 89-4855, 89-4856, 89-4857, 89-9050, 89-9051, 89-9052, 89-9053, 89-9054, 89-9055, 89-9056, 89-9057, 89-9100, 89-9101, 89-9102, 89-9103, 89-9104, 89-9105, 89-9106, 89-9107, 89-9150, 89-9151, 89-9152, 89-9153, 89-9154, 89-9155, 89-9156, 89-9157, 89-9200, 89-9201, 89-9202, 89-9203, 89-9204, 89-9205, 89-9206, 89-9207, 89-9210, 89-9211, 89-9212, 89-9213, 89-9214, 89-9215, 89-9216, 89-9217, 89-9500, 89-9501, 89-9502, 89-9503, 89-9504, 89-9505, 89-9506, 89-9507, 89-4030, 89-4031, 89-4032, 89-4033, 89-4034, 89-4035, 89-4036, 89-4037, 89-4050, 89-4051, 89-4052, 89-4053, 89-4054, 89-4055, 89-4056, 89-4057, 89-4080, 89-4081, 89-4082, 89-4083, 89-4084, 89-4085, 89-4086, 89-4087, 89-4100, 89-4101, 89-4102, 89-4103, 89-4104, 89-4105, 89-4106, 89-4107, 89-4920, 89-4921, 89-4922, 89-4923, 89-4924, 89-4925, 89-4926, 89-4927, 89-4420, 89-4421, 89-4422, 89-4423, 89-4424, 89-4425, 89-4426, 89-4427, 89-4450, 89-4451, 89-4452, 89-4453, 89-4454, 89-4455, 89-4456, 89-4457, 89-4230, 89-4231, 89-4232, 89-4233, 89-4234, 89-4235, 89-4236, 89-4237, 89-4250, 89-4251, 89-4252, 89-4253, 89-4254, 89-4255, 89-4256, 89-4257, 89-4280, 89-4281, 89-4282, 89-4283, 89-4284, 89-4285, 89-4286, 89-4287, 89-4210, 89-4211, 89-4212, 89-4213, 89-4214, 89-4215, 89-4216, 89-4217
Funnels	35-6050, 19-0001S
Drosophila Plugs	51-0505, 51-0805, 51-17725
Cell Culture Flasks	07-8025, 07-8075, 07-8175, 07-9025, 07-9075, 07-9175
Cell Culture Dishes	07-3035, 07-3060, 07-3100, 07-3150

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Biologix Plastics (Changzhou) Co., Ltd.

Product Name	Type
Cell Culture Plates	07-6006, 07-6012, 07-6024, 07-6048, 07-6096
Serological Pipettes	07-5001, 07-5002, 07-5005, 07-5010, 07-5025, 07-5050
Filter Tips	22-0010, 22-0011, 23-0010, 23-0011, 22-0200, 22-0201, 23-0200, 23-0201, 22-1000, 22-1001, 23-1000, 23-1001, 23-0010A, 23-0010H, 23-0011H, 23-0011S, 23-0020A, 23-0021S, 23-0051S, 23-0100A, 23-0101S, 23-0200A, 23-0200A1, 23-0200A2, 23-0200H, 23-0201H, 23-0201S, 23-1000A, 23-1000H, 23-1001A, 23-1001S, 23-1250H, 23-0010B, 23-0011B, 23-0200B, 23-0201B, 23-0100, 23-1010, 23-0010S, 23-0200S
Deep-well Plates	02-1016, 02-1022, 02-2010, 02-1116, 02-1216, 02-1316, 02-1122, 02-1222, 02-1322, 02-2110, 02-2210, 02-2310, 02-6022, 02-6122, 02-6222, 02-6322, 02-1022, 02-7122, 02-7222, 02-7322, 02-8005, 02-8105, 02-8205, 02-8305, 02-9010, 02-9110, 02-9210, 02-9310, 02-0096, 02-0196, 02-0008
Reagent Bottles	04-2008, 04-3008, 04-2015, 04-3015, 04-2030, 04-3030, 04-2060, 04-3060, 04-2125, 04-3125, 04-2250, 04-3250, 04-2500, 04-3500, 04-2100, 04-3100, 04-0005, 04-1005, 04-0010, 04-1010, 04-0015, 04-1015, 04-0030, 04-1030, 04-0060, 04-1060, 04-0125, 04-1125, 04-0200, 04-1200, 04-0250, 04-1250, 04-0500, 04-1500
Gloves	97-1111, 97-1112, 97-1113, 97-1114, 97-1115, 97-6111, 97-6112, 97-6113, 97-6114, 97-6115
Sealing Films	61-0010, 61-0110, 61-0013, 61-0012, 61-0015, 61-0014, 61-0011, 61-0120, 61-0121, 61-0125, 61-0030, 61-0031, 61-0040, 61-0041, 61-0210, 61-0250, 61-0020, 61-0025, 61-0080, 61-0081, 61-0145, 61-0050, 61-0051, 61-0152, 61-0153, 61-0060, 61-0061, 61-0070, 61-0071, 61-0072, 61-0301, 61-0302, 61-0303, 61-0304, 61-0130, 61-0131, 61-0132, 61-0410, 61-0411
Waste Fluid Collection System	05-2720, 05-2721, 05-2791, 05-2792, 05-2793, 05-2794, 05-2797, 05-2798
Cell Culture Slides	07-2101, 07-2102, 07-2104, 07-2108
Swab	RH-2018, RH-2019, 10028, 905101, 901101, 71-0121, 71-0122

This annex is only valid if attached to the report mentioned above.