



ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«ЕАС AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060

Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru



№ 005032

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.03842

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

(юридический адрес лица)

143906, Россия, Московская область, г. Балашиха, квартал Щитниково, д. 88А

(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «Агат-Мед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к разработке, производству и продаже медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:

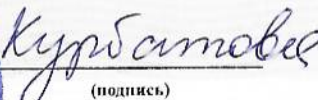

(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.




(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ
ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "ЕАС AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ



ФЕДЕРАЛЬНОЕ АГЕНТСТВО
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СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1

ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028

ИНН 7717616798 ОГРН 1087746489060

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Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru



РАЗРЕШЕНИЕ на применение знака соответствия системы добровольной сертификации ГОСТ Р «EAC AUDIT»

Регистрационный номер № 04EAC1.CM.03842

ВЫДАНО НА ОСНОВАНИИ РЕШЕНИЯ О ВЫДАЧЕ СЕРТИФИКАТА СООТВЕТСТВИЯ
СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА ИЗДЕЛИЙ МЕДИЦИНСКИХ

Общество с ограниченной ответственностью «Агат-Мед»

(наименование лица)

105173, Россия, г. Москва, ул. Главная, д. 6, кв. 12

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(фактический адрес лица)

ИНН: 7719187311

ОГРН: 1037739078970

РАЗРЕШАЕТ

Применять знак соответствия системы добровольной сертификации «EAC AUDIT» на период действия сертификата соответствия № 04EAC1.CM.03842 в любой форме, исключаяющей возможность толкования его как знака соответствия качества продукции. Допускается использовать знак соответствия в рекламных буклетах, проспектах, брошюрах, плакатах, бланках организационно-распорядительной документации организации – держателя сертификата.

Руководитель органа
по сертификации:

(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.



(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ
ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «EAC AUDIT» И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ



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«EAC AUDIT»

РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1

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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-02

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Гладун Виталий Викторович

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
по сертификации:

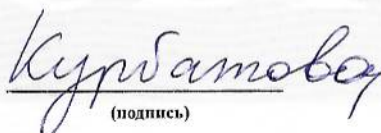

(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.




(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С
ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ
ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «EAC AUDIT» И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ



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СЕРТИФИКАТ СООТВЕТСТВИЯ АУДИТОРА

Регистрационный номер № 04EAC1.CM.03842-03

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ, ЧТО

Нефуков Юрий Николаевич

соответствует требованиям системы добровольной сертификации «EAC AUDIT», предъявляемым к аудиторам внутренних проверок системы менеджмента качества изделий медицинских на соответствие стандарту ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования»

Дата регистрации: 08-09-2021

Срок действия до: 07-09-2024

Руководитель органа
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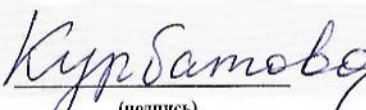

(подпись)

В. И. Погодин

Председатель
экспертной комиссии:

М.П.




(подпись)

Е. Д. Курбатова

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

CERTIFIED COMPANY UNI EN ISO 9001:2008 & UNI CEI EN ISO 13485:2012

DICHIARAZIONE DI CONFORMITA' CE **CE DECLARATION OF CONFORMITY**

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

DICHIARA
DECLARES

Che il dispositivo medico diagnostico in vitro di seguito descritto:
That in vitro diagnostic medical devices described as follows:

CONTENITORI PER CAMPIONI BIOLOGICI **SPECIMEN CONTAINERS**

PRODOTTI NON STERILI – NOT STERILE PRODUCTS

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

- > **Sono conformi ai requisiti essenziali di cui all'allegato I della direttiva 98/79/CE del 27 ottobre 1998 recepita con il D.Lgs 332 del 08/09/2000.**
Are manufactured in compliance with essential requirements of Annex 1 of the 98/79/CE Directive dated 27th October 1998 put into force by D.Lgs. 332 dated 08/09/2000.
- > **I Dispositivi di cui all'Allegato 1 non rientrano nell'elenco A o B di cui all'Allegato II della Direttiva 98/79/CE.**
The devices as per Annex 1 do not do not fall under list A or B of annex II of the Directive 98/79/EC.
- > **La presente dichiarazione è stata redatta in conformità all'Allegato III (escluso punto 6) della Direttiva 98/79/CE.**
The present Declaration was drafted in accordance with annex III to Directive 98/79/EC.

Rilasciato / Released
Canelli, 26.07.2015

Dulio BEONO
Responsabile Assicurazione Qualità

ALLEGATO 1 alla Dichiarazione di Conformità 98/79/CE

Annex 1 to Declaration of Conformity 98/79/CE

COD.	DESCRIZIONE	DESCRIPTION
1011	Contenitori per feci 18ml, PS, con tappo a pressione con paletta	Faeces containers 18ml, PS, with pressure cap and spoon
1011/E	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	Faeces containers 18ml, PS, with pressure cap and spoon, with label
1011/E/50	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta, in confezioni da 50 pezzi	Faeces containers 18ml, PS, with pressure cap and spoon, with label, in bags of 50 pieces
1011/E/AST	Contenitori per feci 18ml, PS, con tappo a pressione con paletta, con etichetta	Faeces containers 18ml, PS, with pressure cap and spoon, with label
1012	Contenitori per campioni biologici 18ml, PS, con tappo a pressione	Specimen containers 18ml, PS, with pressure cap
1013	Contenitori da 18ml, PS, senza tappo	Containers 18ml, PS, without cap
1030	Contenitori per urine 130ml, PS, graduati, tappo a pressione	Graduated urine containers 130ml, PS, pressure cap
1030/E	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta	Graduated urine containers 130ml, PS, pressure cap, with label
1030/E/CS	Contenitori per urine 130ml, PS, graduati, tappo a pressione, con etichetta, confezione singola	Graduated urine containers 130ml, PS, pressure cap, with label, individually wrapped
1030/MO	Contenitori per urine 130ml, PP, graduati, tappo a pressione	Graduated urine containers 130ml, PP, pressure cap
1030/MO/E	Contenitori urina 130ml, in PP tappo a pressione, graduati, etichetta	Graduated urine containers 130ml, PP, pressure cap, label
1030/MO/T	Contenitori urina 130ml, in PP tappo a pressione inserito, graduati	Graduated urine containers 130ml, PP, pressure cap
1030/R	Contenitori per urine 130ml, PS, graduati, tappo a pressione rosso	Graduated urine containers 130ml, PS, red pressure cap
1030/S	Contenitori per urine 130ml, PS, graduati, senza tappo	Graduated urine containers 130ml, PS, without cap
1030/T	Contenitori per urine 130ml, PS, graduati, tappo a pressione inserito	Graduated urine containers 130ml, PS, with inserted pressure cap
1040	Contenitori per urina 120ml, PP, con coperchio autoadesivo	Graduated urine containers 120ml, PP, with self-adhesive cap
1040/P	Contenitori per urina 120ml, PS, con coperchio autoadesivo	Graduated urine containers 120ml, PS, with self-adhesive cap
1040/P/S	Contenitori per urina 120ml, PS, senza coperchio autoadesivo	Graduated urine containers 120ml, PS, without self-adhesive cap
1040/S	Contenitori per urina 120ml, PP, senza coperchio autoadesivo	Graduated urine containers 120ml, PP, without self-adhesive cap
1041	Contenitori per campioni biologici 30ml, PS, con tappo a pressione	Specimen containers 30ml, PS, with pressure cap
1041/E	Contenitori per campioni biologici 30ml, PS, con tappo a pressione, con etichetta	Specimen containers 30ml, PS, with pressure cap, with label
1041/S	Contenitori per campioni biologici 30ml, PS, senza tappo	Specimen containers 30ml, PS, without cap
1041/T	Contenitori per campioni biologici 30ml, PS, con tappo a pressione inserito	Specimen containers 30ml, PS, with inserted pressure cap
1050	Contenitori per urine 150ml, PS, graduati, tappo a pressione	Graduated urine containers 150ml, PS, pressure cap
1050/E	Contenitori per urine 150ml, PS, graduati, tappo a pressione, con etichetta	Graduated urine containers 150ml, PS, pressure cap, with label
1050/S	Contenitori per urine 150ml, PS, graduati, senza tappo	Graduated urine containers 150ml, PS, without cap
1050/T	Contenitori per urine 150ml, PS, graduati, tappo a pressione inserito	Graduated urine containers 150ml, PS, with inserted pressure cap
1051	Contenitori per espettorato 60ml, PS, con tappo a pressione	Sputum containers 60ml, PS, with pressure cap
1051/E	Contenitori per espettorato 60ml, PS, con tappo a pressione, con etichetta	Sputum containers 60ml, PS, with pressure cap, with label
1051/S	Contenitori per espettorato 60ml, PS, senza tappo a pressione	Sputum containers 60ml, PS, without pressure cap
1051/S/CS	Contenitori per espettorato 60ml, PS, senza tappo a pressione, in confezione singola	Sputum containers 60ml, PS, without pressure cap, individually wrapped
1051/T	Contenitori per espettorato 60ml, PS, con tappo a pressione inserito	Sputum containers 60ml, PS, with inserted pressure cap
1061	Contenitori per campioni biologici 35ml, PS, con tappo a pressione	Specimen containers 35ml, PS, with pressure cap
10621	Contenitori rotondi "SECURBOX" da 2.000ml, in PP, con coperchio a pressione in PP e sigillo di sicurezza a strappo. Con supporto di materiale assorbente a 10 fori. Con manico	Disposable container SECURBOX 2,000 ml in PP, with lid in PP with security tear seal. It contains inside absorbent material with 10 holes. With handle
10622	Contenitori rettangolari "SECURBOX" da 5.000ml, in PP, con coperchio a pressione in PP e sigillo di sicurezza a strappo. Con supporto di materiale assorbente a 99 fori. Con manico	Disposable container SECURBOX 5,000 ml in PP, with lid in PP with security tear seal. It contains inside absorbent material with 99 holes. With handle
10631	Contenitori da 5ml, PE, tappo a vite	Containers 5ml, PE, screw cap
10632	Contenitori da 30ml, PE, tappo a vite	Containers 30ml, PE, screw cap
10633	Contenitori da 90ml, PE, tappo a vite	Containers 90ml, PE, screw cap

Contenitori per campioni biologici – Prodotti non Sterili

Specimen Containers – Not Sterile products

Cod.	DESCRIZIONE	DESCRIPTION
1070	Contentitori modello iBijou da 7ml, in PS, N20x50mm, con tappo a vite	Containers iBijou type in PS, 7ml, N20x50 mm, with screw cap
1070/E	Contentitori modello iBijou da 7ml, in PS, N20x50mm, con tappo a vite, con etichetta	Containers iBijou type in PS, 7ml, N20x50 mm, with screw cap, with label
1081	Contentitori per urine 150ml, PS, graduati, tappo a vite	Graduated urine containers 150ml, PS, screw cap
1081/CS	Contentitori per urine 150ml, PS, graduati, tappo a vite, in confezione singola	Graduated urine containers 150ml, PS, screw cap, individually wrapped
1081/E	Contentitori per urine 150ml, PS, graduati, tappo a vite, con etichetta	Graduated urine containers 150ml, PS, screw cap, with label
1081/T	Contentitori urina 150ml, in PS con tappo a vite inserito,	Graduated urine containers 150ml, PS, screw cap
1211	Contentitori per feci 60ml, PS, con tappo a pressione con paletta	Faeces containers 60ml, PS, with pressure cap and spoon
1211/CS	Contentitori per feci 60ml, PS, con tappo a pressione con paletta	Faeces containers 60ml, PS, with pressure cap and spoon
1212	Contentitori per campioni biologici 60ml, PS, con tappo a pressione	Specimen containers 60ml, PS, with pressure cap
1212/CS	Contentitori per campioni biologici 60ml, PS, con tappo a pressione, confezione singola	Specimen containers 60ml, PS, with pressure cap, individually wrapped
1213	Contentitori da 60ml, PS, senza tappo	Containers 60ml, PS, without cap
1230	Contentitori per urine 200ml, PS, graduati, tappo a vite	Graduated urine containers 200ml, PS, screw cap
1230/10	Contentitori per urine 200ml, PS, graduati, tappo a vite	Graduated urine containers 200ml, PS, screw cap
1230/100	Contentitori per urine 200ml, PS, graduati, tappo a vite	Graduated urine containers 200ml, PS, screw cap
1230/CS	Contentitori per urine 200ml, PS, graduati, tappo a vite, confezione singola	Graduated urine containers 200ml, PS, screw cap, ind. wrapped
1230/E	Contentitori per urine 200ml, PS, graduati, tappo a vite, con etichetta	Graduated urine containers 200ml, PS, screw cap, with label
1230/S/E	Contentitori urina 200ml, in PS senza tappo, graduati,	Graduated urine containers 200ml, PS, with label
1230/T	Contentitori urina 200ml, in PS tappo a vite inserito,	Graduated urine containers 200ml, PS, with inserted screw cap
1230/TE	Contentitori per urine 200ml, PS, graduati, tappo a vite inserito, con etichetta	Graduated urine containers 200ml, PS, with inserted screw cap, with label
12731	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated
12731/E	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata, etichetta	Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, with label
12731/SAC	Taniche in PE da 2.500ml per la raccolta urine 24ore,	Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, individually wrapped
12731K	Tanica per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	Tanks for 24 hours urine collection, 2.500ml, PE, screw cap, graduated
14120	Contentitori per istologia da 20ml, in PP, tappo a vite verde	20 ml Surgical specimen containers in PP, with yellow screw cap
14120/B	Contentitori per istologia da 20ml, in PP, tappo a vite giallo, etichetta biohazard	20 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label
14121	Contentitori per istologia da 40ml, in PP, tappo a vite giallo	40 ml Surgical specimen containers in PP, with yellow screw cap
14121/B	Contentitori per istologia da 40ml, in PP, tappo a vite giallo, etichetta biohazard	40 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label
14122	Contentitori per istologia da 60ml, in PP, tappo a vite giallo	60 ml Surgical specimen containers in PP, with yellow screw cap
14122/B	Contentitori per istologia da 60ml, in PP, tappo a vite giallo, etichetta biohazard	60 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label
14123	Contentitori per istologia da 90ml, in PP, tappo a vite giallo	90 ml Surgical specimen containers in PP, with yellow screw cap
14123/B	Contentitori per istologia da 90ml, in PP, tappo a vite giallo, etichetta biohazard	90 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label
14124	Contentitori per istologia da 120ml, in PP, tappo a vite giallo	120 ml Surgical specimen containers in PP, with yellow screw cap
14124/B	Contentitori per istologia da 120ml, in PP, tappo a vite giallo, etichetta biohazard	120 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label
14131	Contentitori per biopsie in PS, con tappo a pressione in PE, da 30ml	Biopsy specimen containers in PS with pressure cap in PE, 30 ml
14132	Contentitori per biopsie in PS, con tappo a pressione in PE, da 50ml	Biopsy specimen containers in PS with pressure cap in PE, 50 ml
14134	Contentitori per biopsie in PS, con tappo a pressione in PE, da 100ml	Biopsy specimen containers in PS with pressure cap in PE, 100 ml
14136	Contentitori per biopsie in PS, con tappo a pressione in PE, da 150ml	Biopsy specimen containers in PS with pressure cap in PE, 150 ml
14138	Contentitori per biopsie in PS, con tappo a pressione in PE, da 200ml	Biopsy specimen containers in PS with pressure cap in PE, 200 ml
14140	Contentitori per biopsie in PS, con tappo a pressione in PE, da 250ml	Biopsy specimen containers in PS with pressure cap in PE, 250 ml
14142	Contentitori per pezzi chirurgici 500ml, PE, bocca larga, tappo a pressione	Surgical specimens containers 500ml, PE, wide opening, with pressure cap

COD.	DESCRIZIONE	DESCRIPTION
14142/B	Contenitori per pezzi chirurgici 500ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	Surgical specimens containers 500ml, PE, wide opening, with pressure cap, Biohazard label
14143	Contenitori per pezzi chirurgici 1.000ml, PE, bocca larga, tappo a pressione	Surgical specimens containers 1.000ml, PE, wide opening, with pressure cap
14143/B	Contenitori per pezzi chirurgici 1.000ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	Surgical specimens containers 1.000ml, PE, wide opening, with pressure cap, Biohazard label
14144	Contenitori per pezzi chirurgici 1.500ml, PE, bocca larga, tappo a pressione	Surgical specimens containers 1.500ml, PE, wide opening, with pressure cap
14144/B	Contenitori per pezzi chirurgici 1.500ml, PE, bocca larga, tappo a pressione, etichetta Biohazard	Surgical specimens containers 1.500ml, PE, wide opening, with pressure cap, Biohazard label
14150	Contenitori trasparenti per pezzi chirurgici 150ml, PP, tappo a pressione	Surgical specimens transparent containers 150ml, PP, with pressure cap
14150/B	Contenitori trasparenti per pezzi chirurgici 150ml, PP, tappo a pressione, etichetta Biohazard	Surgical specimens transparent containers 150ml, PP, with pressure cap, Biohazard label
14151	Contenitori per istologia da 250ml, in PP, tappo a vite giallo	250 ml Surgical specimen containers in PP, with yellow screw cap
14151/B	Contenitori per istologia da 250ml, in PP, tappo a vite giallo, etichetta biohazard	250 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label
14152	Contenitori per istologia da 500ml, in PP, tappo a vite giallo	500 ml Surgical specimen containers in PP, with yellow screw cap
14152/B	Contenitori per istologia da 500ml, in PP, tappo a vite giallo, etichetta biohazard	500 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label
14153	Contenitori per istologia da 1000 ml, in PP, tappo a vite giallo	1000 ml Surgical specimen containers in PP, with yellow screw cap
14153/B	Contenitori per istologia da 1000 ml, in PP, tappo a vite giallo, etichetta biohazard	1000 ml Surgical specimen containers in PP, with yellow screw cap, biohazard label
14155	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione	Surgical specimens transparent containers 250ml, PP, with pressure cap
14155/B	Contenitori trasparenti per pezzi chirurgici 250ml, PP, tappo a pressione, etichetta Biohazard	Surgical specimens transparent containers 250ml, PP, with pressure cap, Biohazard label
14160	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione	Surgical specimens transparent containers 500ml, PP, with pressure cap
14160/S	Contenitori trasparenti per pezzi chirurgici 500ml, PP, tappo a pressione, serigrafati	Surgical specimens transparent containers 500ml, PP, with pressure cap, serigraphed
14170	Contenitori trasparenti per pezzi chirurgici 1.000ml, PP, tappo a pressione	Surgical specimens transparent containers 1.000ml, PP, with pressure cap
14170/S	Contenitori trasparenti per pezzi chirurgici 1.000ml, PP, tappo a pressione, serigrafati	Surgical specimens transparent containers 1.000ml, PP, with pressure cap, serigraphed
14175	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione	Surgical specimens transparent containers 2.000ml, PP, with pressure cap
14175/B	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione, etichetta Biohazard	Surgical specimens transparent containers 2.000ml, PP, with pressure cap, Biohazard label
14175/T	Contenitori trasparenti per pezzi chirurgici 2.000ml, PP, tappo a pressione inserito	Surgical specimens transparent containers 2.000ml, PP, with inserted pressure cap
14180	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione	Surgical specimens transparent containers 3.000ml, PP, with pressure cap
14180/B	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione, etichetta Biohazard	Surgical specimens transparent containers 3.000ml, PP, with pressure cap, Biohazard label
14180/S	Contenitori trasparenti per pezzi chirurgici 3.000ml, PP, tappo a pressione, serigrafati	Surgical specimens transparent containers 3.000ml, PP, with pressure cap, serigraphed
14185	Contenitori trasparenti per pezzi chirurgici 5.000ml, PP, tappo a pressione	Surgical specimens transparent containers 5.000ml, PP, with pressure cap
14185/B	Contenitori trasparenti per pezzi chirurgici 5.000ml, PP, tappo a pressione, etichetta Biohazard	Surgical specimens transparent containers 5.000ml, PP, with pressure cap, Biohazard label
14190	Contenitori per grossi pezzi chirurgici 5.600ml, PP, tappo a pressione	Big surgical specimens containers 5.600ml, PP, with pressure cap
14190/B	Contenitori per grossi pezzi chirurgici 5.600ml, PP, tappo a pressione, etichetta biohazard	Big surgical specimens containers 5.600ml, PP, with pressure cap, biohazard label
14192	Contenitori per grossi pezzi chirurgici 2,500ml, PP, tappo a pressione	Big surgical specimens containers 2,500ml, PP, with pressure cap
14192/B	Contenitori per grossi pezzi chirurgici 2,500ml, PP, tappo a pressione, etichetta biohazard	Big surgical specimens containers 2,500ml, PP, with pressure cap, biohazard label
14195	Contenitori per grossi pezzi chirurgici 11.000ml, PP, tappo a pressione	Big surgical specimens containers 11.000ml, PP, with pressure cap
14195/B	Contenitori per grossi pezzi chirurgici 11.000ml, PP, tappo a pressione, etichetta biohazard	Big surgical specimens containers 11.000ml, PP, with pressure cap, biohazard label
1560	Contenitori per saliva 30 ml, in PP, tappo a vite,	Autoclavable sputum collection container 30 ml, in PP, screw cap
1630	Contenitori da 250 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm	250 ml specimen containers in PS. With aluminium screw cap with gasket, Ø39 x 60 mm
1630/E	Contenitori da 250 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm, con etichetta	250 ml specimen containers in PS. With aluminium screw cap with gasket, Ø39 x 60 mm, with label
19550	Contenitore per la raccolta delle urine per test antidoping	Urine containers for testing drugs abuse

Cod.	DESCRIZIONE	DESCRIPTION
2030	Contenitori per campioni biologici 30ml, PP, tappo a vite	Specimen containers 30ml, PP, with screw cap
2030/E	Contenitori per campioni biologici 30ml, PP, tappo a vite, etichetta	Specimen containers 30ml, PP, with screw cap, label
2030/P	Contenitori per campioni biologici 30ml, PP, tappo a vite rosso non inserito	Specimen containers 30ml, PP, with red screw cap not inserted
2030/S	Contenitori per campioni biologici 30ml, PP, con tappo a vite a parte	Specimen containers 30ml, PP, with screw cap in separate bag
2030/S/R	Contenitori per campioni biologici 30ml, PP, con tappo a vite a parte rosso	Specimen containers 30ml, PP, with red screw cap in separate bag
2040	Contenitori per campioni biologici 60ml, PS, tappo a vite	Specimen containers 60ml, PS, with screw cap
2040/B	Contenitori per campioni biologici 60ml, PS, tappo a vite bianco	Specimen containers 60ml, PS, with white screw cap
2040/E	Contenitori per campioni biologici 60ml, PS, tappo a vite, con etichetta	Specimen containers 60ml, PS, with screw cap, with label
2040/E/R	Contenitori campioni biologici 60ml, PS, tappo inserito rosso	Specimen containers 60ml, PS, with screw cap, with label
2040/P	Contenitori campioni biologici 60ml, in PS, Ø35 x 70 mm,	Specimen containers 60ml, PS, with screw cap
2040/P/E	Contenitori campioni biologici 60ml, PS, Ø35x70mm, etichetta,	Specimen containers 60ml, PS, with screw cap, with label
2040/R	Contenitori per campioni biologici 60ml, PS, tappo a vite rosso	Specimen containers 60ml, PS, with red screw cap
2042	Contenitori per campioni biologici 60ml, PS, tappo a vite e paletta	Specimen containers 60ml, PS, with screw cap and spoon
2042/E	Contenitori per campioni biologici 60ml, PS, tappo a vite e paletta, con etichetta	Specimen containers 60ml, PS, with screw cap and spoon, with label
2050	Contenitori per campioni biologici 60ml, PP, tappo a vite	Specimen containers 60ml, PP, with screw cap
2050/100	Contenitori per campioni biologici 60ml, PP, tappo a vite	Specimen containers 60ml, PP, with screw cap
2050/B	Contenitori di colore blu per campioni biologici 60ml, PP, tappo a vite	Specimen containers blue colour 60ml, PP, with screw cap
2050/C	Tappi a vite colore giallo per contenitori cod. 2050	Yellow screw cap for containers cod 2050
2050/CS	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	Specimen containers 60ml, PP, with screw cap, ind. wrapped
2050/DDK	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito rosso	Specimen containers 60ml, PP, with red inserted screw cap
2050/E	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito, con etichetta	Specimen containers 60ml, PP, with inserted screw cap, with label
2050/E/S	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito, con etichetta	Specimen containers 60ml, PP, with screw cap not inserted, with label
2050/P	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito	Specimen containers 60ml, PP, with screw cap not inserted
2050/P/E	Contenitori campioni biologici 60ml, PP, Ø35x70mm, graduati,	Specimen containers 60ml, PP, with screw cap not inserted
2050/PR	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito colore rosso	Specimen containers 60ml, PP, with screw cap not inserted red colour
2050/R	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito colore rosso	Specimen containers 60ml, PP, with screw cap inserted red colour
2050/S	Contenitori per campioni biologici 60ml, PP, senza tappo	Specimen containers 60ml, PP, without cap
2050/T	Contenitori per campioni biologici 60ml, PP, tappo a vite inserito	Specimen containers 60ml, PP, with inserted screw cap
2050/TAPPO/B	Tappi a vite colore blu per contenitori cod. 2050	Blue screw cap for containers cod 2050
2050P	Contenitori per campioni biologici 60ml, PP, tappo a vite non inserito	Specimen containers 60ml, PP, with screw cap not inserted
2052	Contenitori per feci 60ml, PP, con tappo a vite con paletta	Faeces containers 60ml, PP, with screw cap and spoon
2052/10	Contenitori per feci 60ml, PP, con tappo a vite con paletta	Faeces containers 60ml, PP, with screw cap and spoon
2052/100	Contenitori per feci 60ml, PP, con tappo a vite con paletta	Faeces containers 60ml, PP, with screw cap and spoon
2052/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, confezione singola	Faeces containers 60ml, PP, with screw cap and spoon, individually wrapped
2052/E	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta	Faeces containers 60ml, PP, with screw cap and spoon, with label
2052/E/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta, confezione singola	Faeces containers 60ml, PP, with screw cap and spoon, with label, individually wrapped
2052/R	Contenitori per feci 60ml, PP, con tappo a vite rosso con paletta	Faeces containers 60ml, PP, with red screw cap and spoon
2052/T5	Contenitori per feci 60ml, PP, con tappo a vite con paletta	Faeces containers 60ml, PP, with screw cap and spoon
2062	Contenitori per feci da 60 ml, in PP, tappo a vite	Faeces containers in PP 60ml, screw cap
2062/10	Contenitori per feci da 60 ml, in PP, tappo a vite	Faeces containers in PP 60ml, screw cap
2062/E	Contenitori per feci da 60ml, in PP, tappo vite con paletta, etichetta	Faeces containers in PP 60ml, screw cap, with label
2062/P	Contenitori per feci da 60 ml, in PP, tappo a vite a parte	Faeces containers in PP 60ml, not assembled screw cap

Contenitori per campioni biologici – Prodotti non Sterili

Specimen Containers – Not Sterile products

26.07.2015

Cod.	DESCRIZIONE	DESCRIPTION
2072	Contenitori per feci da 60 ml, in PS, tappo a vite	Faeces containers in PS 60ml, screw cap
2072/E	Contenitori per feci da 60ml, in PS, tappo vite con paletta, etichetta	Faeces containers in PS 60ml, screw cap, with label
2072/P	Contenitori per feci da 60 ml, in PS, tappo a vite a parte	Faeces containers in PS 60ml, not assembled screw cap
2120	Contenitori per urine 150ml, PP, graduati, tappo a vite	Graduated urine containers 150ml, PP, screw cap
2120/100	Contenitori per urine 150ml, PP, graduati, tappo a vite	Graduated urine containers 150ml, PP, screw cap
2120/50	Contenitori per urine 150ml, PP, graduati, tappo a vite	Graduated urine containers 150ml, PP, screw cap
2120/B	Contenitori per urine 150ml, PP, graduati, tappo a vite bianco	Graduated urine containers 150ml, PP, white screw cap
2120/CS	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic
2120/CS/M	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic
2120/CS/MI	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici	Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic
2120/E	Contenitori per urine 150ml, PP, graduati, tappo a vite, con etichetta	Graduated urine containers 150ml, PP, screw cap, with label
2120/E/CS	Contenitori per urine 150ml, PP, graduati, tappo a vite, confezione singola, asettici, con etichetta	Graduated urine containers 150ml, PP, screw cap, ind. Wrapped, aseptic, with label
2120/ES	Contenitori per urine 150ml, PP, graduati, tappo a vite, con etichetta non applicata	Graduated urine containers 150ml, PP, screw cap, with label in separate bag
2120/N	Contenitori per urine 150ml, PP, graduati, tappo a vite neutro	Graduated urine containers 150ml, PP, neutral screw cap
2120/R	Contenitori per urine 150ml, PP, graduati, tappo a vite rosso	Graduated urine containers 150ml, PP, red screw cap
2120/S	Contenitori per urine 150ml, PP, graduati, senza tappo	Graduated urine containers 150ml, PP, without cap
2120/T	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito	Graduated urine containers 150ml, PP, with inserted screw cap
2120/T/100	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 100 pcs	Graduated urine containers 150ml, PP, with inserted screw cap, bags of 100 pcs
2120/T/N	Contenitore urina 150ml, in PP tappo a vite neutro inserito,	Graduated urine containers 150ml, PP, with inserted screw cap
2120/T5	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 5 pcs	Graduated urine containers 150ml, PP, with inserted screw cap, bags of 5 pcs
2120/T50	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito, confezioni da 50 pcs	Graduated urine containers 150ml, PP, with inserted screw cap, bags of 50 pcs
2120/TB	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito bianco	Graduated urine containers 150ml, PP, with inserted white screw cap
2120/TB	Contenitori urina 150ml, in PP con tappo a vite bianco	Graduated urine containers 150ml, PP, with inserted screw cap
2120/TE	Contenitori urina 150ml, in PP tappo vite azzurro inserito,	Graduated urine containers 150ml, PP, with inserted screw cap
2120/TN	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito di colore neutro	Graduated urine containers 150ml, PP, with inserted screw cap neutral colour
2120/TR	Contenitori per urine 150ml, PP, graduati, tappo a vite inserito colore rosso	Graduated urine containers 150ml, PP, with red inserted screw cap
2120/V/500	Contenitori per urine 150ml, PP, graduati, tappo a vite verde	Graduated urine containers 150ml, PP, screw cap green colour
2220	Contenitori per urine 200ml, PP, graduati, tappo a vite	Graduated urine containers 200ml, PP, screw cap
2220/250	Contenitori urina 200ml, in PP tappo a vite, graduati,	Graduated urine containers 200ml, PP, screw cap
2220/CS	Contenitori per urine 200ml, PP, graduati, tappo a vite, confezione singola	Graduated urine containers 200ml, PP, screw cap, ind. wrapped
2220/E	Contenitori per urine 200ml, PP, graduati, tappo a vite, con etichetta	Graduated urine containers 200ml, PP, screw cap, with label
2220/E/CS	Contenitori per urine 200ml, PP, graduati, tappo a vite, con etichetta, confezione singola	Graduated urine containers 200ml, PP, screw cap, with label, individually wrapped
2220/R	Contenitori per urine 200ml, PP, graduati, tappo a vite rosso	Graduated urine containers 200ml, PP, red screw cap
2220/S	Contenitori per urine 200ml, PP, graduati, senza tappo a vite	Graduated urine containers 200ml, PP, without screw cap
2220/T	Contenitori per urine 200ml, PP, graduati, tappo a vite inserito	Graduated urine containers 200ml, PP, with inserted screw cap
2250	Contenitori campioni biologici da 40 ml, in PP	Specimen containers 40 ml, in PP
2420	Contenitori per urine 150ml, PP, graduati, tappo a vite e tappino per prelievo campioni	Graduated urine containers 150ml, PP, screw cap and plug
2420/R	Contenitori per urine 150ml, PP, graduati, tappo a vite rosso e tappino per prelievo campioni	Graduated urine containers 150ml, PP, with screw cap and plug red colour
2420/TR	Contenitori urine 150ml, PP, graduati, tappo a vite rosso e tappino prelievo campioni inserito	Graduated urine containers 150ml, PP, with inserted screw cap and plug red colour
2440	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm.	Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm

Contenitori per campioni biologici – Prodotti non Sterili

Specimen Containers – Not Sterile products

COD.	DESCRIZIONE	DESCRIPTION
2440/CS	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, conf. singola	Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, individually wrapped
2440/E	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, con etichetta	Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, with label
2440/E/CS	Contenitori in PS per campioni biologici con tappo a vite inserito, 60 ml, Ø 38 x 65 mm, con etichetta, conf. singola	Specimen containers in PS with inserted screw cap, 60 ml, Ø 38 x 65 mm, with label, individually wrapped
2440/P	Contenitori campioni biologici 60ml, PS, con tappo a parte,	Specimen containers in PS with screw cap, 60 ml, Ø 38 x 65 mm
2442	Contenitori per feci in PS con tappo a vite e con paletta, 60 ml, Ø 38 x 65 mm	Faeces containers in PS with screw cap and spoon, 60 ml, Ø 38 x 65 mm
2442/E	Contenitori per feci in PS con tappo a vite e con paletta, 60 ml, Ø 38 x 65 mm, con etichetta.	Faeces containers in PS with screw cap and spoon, 60 ml, Ø 38 x 65 mm, with label
2442/R	Contenitori per feci in PS con tappo a vite rosso e con paletta, 60 ml, Ø 38 x 65 mm	Faeces containers in PS with red screw cap and spoon, 60 ml, Ø 38 x 65 mm
2450	Contenitori per campioni biologici 60ml, PP, tappo a vite	Specimen containers 60ml, PP, with screw cap
2450/B	Contenitori per campioni biologici 60ml, PP, tappo a vite bianco	Specimen containers 60ml, PP, with white screw cap
2450/CS	Contenitori per campioni biologici 60ml, PP, tappo a vite, confezione singola	Specimen containers 60ml, PP, with screw cap, ind. wrapped
2450/E	Contenitori per campioni biologici 60ml, PP, tappo a vite, con etichetta	Specimen containers 60ml, PP, with screw cap, with label
2450/P	Contenitori campioni biologici 60ml, in PP, Ø38 x 65 mm,	Specimen containers 60ml, PP, with screw cap, with label
2450/R	Contenitori per campioni biologici 60ml, PP, tappo a vite colore rosso	Specimen containers 60ml, PP, with red screw cap
2452	Contenitori per feci 60ml, PP, con tappo a vite con paletta	Faeces containers 60ml, PP, with screw cap and spoon
2452/E	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta	Faeces containers 60ml, PP, with screw cap and spoon, with label
2452/E/CS	Contenitori per feci 60ml, PP, con tappo a vite con paletta, con etichetta, confezione singola	Faeces containers 60ml, PP, with screw cap and spoon, with label, individually wrapped
2452/R	Contenitori per feci 60ml, PP, con tappo a vite rosso e con paletta	Faeces containers 60ml, PP, with red screw cap and with spoon
2452/T/5	Contenitori per feci 60ml, PP, con tappo a vite con paletta	Faeces containers 60ml, PP, with screw cap and spoon
2580	Contenitori per campioni biologici 25ml, PS, tappo a vite	Specimen containers 25ml, PS, with screw cap
2580/B	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco	Specimen containers 25ml, PS, with white screw cap
2580/E	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	Specimen containers 25ml, PS, with screw cap, with label
2580/E/CS	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta, confezione singola	Specimen containers 25ml, PS, with screw cap, with label, individually wrapped
2580/E/P	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	Specimen containers 25ml, PS, with screw cap not inserted, with label
2580/E/P/W	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	Specimen containers 25ml, PS, with screw cap not inserted, with label
2580/E/W	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta	Specimen containers 25ml, PS, with screw cap, with label
2580/EB	Contenitori per campioni biologici 25ml, PS, tappo a vite, con etichetta bianca	Specimen containers 25ml, PS, with screw cap, with white label
2580/ER	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito, con etichetta	Specimen containers 25ml, PS, with not inserted screw cap, with label
2580/P	Contenitori per campioni biologici 25ml, PS, tappo a vite non inserito	Specimen containers 25ml, PS, with not inserted screw cap
2580/PB	Contenitori campioni biologici 25ml, in PS, Ø25 x 90 mm,	Specimen containers 25ml, PS, with not inserted screw cap
2580/S	Contenitori per campioni biologici 25ml, PS, senza tappo	Specimen containers 25ml, PS, without cap
2580/TAPPO/A	Tappo a vite colore azzurro per contenitori cod. 2580/2680	Light blue screw cap for containers cod. 2580/2680
2580/TBIANCO	Tappo a vite colore bianco per contenitori cod. 2580/2680	White screw cap for containers cod. 2580/2680
2580/W	Contenitori per campioni biologici 25ml, PS, tappo a vite bianco non inserito	Specimen containers 25ml, PS, with white not inserted screw cap
2580P	Contenitori campioni biologici 25ml, PS, con tappo a vite	Specimen containers 25ml, PS, with white not inserted screw cap
2588	Contenitori per feci 25ml, PS, con tappo a vite con paletta	Faeces containers 25ml, PS, with screw cap and spoon
2588/E	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta	Faeces containers 25ml, PS, with screw cap and spoon, with label
2588/E/CS	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta, confezione singola	Faeces containers 25ml, PS, with screw cap and spoon, with label, individually wrapped
2588/EB	Contenitori per feci 25ml, PS, con tappo a vite con paletta, con etichetta bianca	Faeces containers 25ml, PS, with screw cap and spoon, with white label
2588/P	Contenitori per feci 25ml, PS, con tappo a vite con paletta a parte	Faeces containers 25ml, PS, with screw cap and spoon in separate bag
2588P	Paletta in polipropilene bianco	Spoon in white polypropylene

Contenitori per campioni biologici – Prodotti non Sterili

Specimen Containers – Not Sterile products

26.07.2015

COD.	DESCRIZIONE	DESCRIPTION
2640	Contenitori da 60 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm	60 ml specimen containers in PS. With aluminium screw cap with gasket, Ø39 x 60 mm
2640/E	Contenitori da 60 ml per campioni biologici in PS. Con tappo a vite in alluminio con guarnizione, Ø39 x 60 mm, con etichetta	60 ml specimen containers in PS. With aluminium screw cap with gasket, Ø39 x 60 mm, with label
2680	Contenitori per campioni biologici 25ml, PP, tappo a vite	Specimen containers 25ml, PP, with screw cap
2680/E	Contenitori per campioni biologici 25ml, PP, tappo a vite inserito, con etichetta	Specimen containers 25ml, PP, with inserted screw cap, with label
2680/P	Contenitori per campioni biologici 25ml, PP, tappo a vite non inserito	Specimen containers 25ml, PP, with not inserted screw cap
2680/S	Contenitori per campioni biologici 25ml, PP, senza tappo a vite	Specimen containers 25ml, PP, without screw cap
2688	Contenitori per feci 25ml, PP, con tappo a vite con paletta	Faeces containers 25ml, PP, with screw cap and spoon
2688/E	Contenitori per feci 25ml, PP, con tappo a vite con paletta, con etichetta	Faeces containers 25ml, PP, with screw cap and spoon, with label
2688/E/CS	Contenitori per feci 25ml, PP, con tappo a vite con paletta, con etichetta, in confezione singola	Faeces containers 25ml, PP, with screw cap and spoon, with label, individually wrapped
5024	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated
5024/E	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata, etichetta	Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated, with label
5024/F	"24 ore" da 2.500 ml tipo bottiglia in pe	Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap
5024K	Bottiglie per la raccolta delle urine nelle 24 ore, 2.500ml, PE, tappo a vite, graduata	Sampling bottles for 24 hours urine collection, 2.500ml, PE, screw cap, graduated
5050/S	Contenitori per feci da 60ml, in PP, senza tappo	Faeces containers in PP 60ml, without cap
5120	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto.	120 ml urine containers in PP, with screw cap with device for vacuum tube
5120/CS	Contenitore per urine in PP da 120ml, tappo con sistema di prelievo sottovuoto, confezione singola	120 ml urine containers in PP, with screw cap with device for vacuum tube, individually wrapped
5434	Contenitori per la raccolta delle urine nelle 24 ore, 2.000ml, PE, tappo a vite, graduata	Square containers for 24 hours urine collection, 2.500ml, PE, graduated, screw cap
5434/M	Contenitori per la raccolta delle urine nelle 24 ore, 2000ml, PE, tappo vite, graduata, marrone	Square containers for 24 hours urine collection, 2.500ml, PE, graduated, screw cap, brown
5471	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, con tappo per il prelievo con provetta tipo sottovuoto	2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle. Screw cap complete of sampling device for vacuum test tubes.
5472	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto	2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes.
5671	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	2000ml Square graduated containers for 24 hours urine collection with ergonomic handle. Screw cap complete of sampling device for vacuum test tubes and sampling probe
5672	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 2000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	2000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes and sampling probe
5731	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 3000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto	3.000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes
5732	Bottiglie graduate ergonomiche per la raccolta delle urine nelle 24 ore, da 3000ml, colore ambrato, con tappo per il prelievo con provetta tipo sottovuoto e sonda prelievo	3.000 ml Square graduated containers for 24 hours urine collection with ergonomic handle, brown colour. Screw cap complete of sampling device for vacuum test tubes and sampling probe
6840	Contenitore per trasporto campioni con coperchio ermetico	Test tubes securbox with hermetic lid

Dulio BEONO

Responsabile Assicurazione Qualità

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro.

Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language.

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date

1998-07-23

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Rinnovo
Renewal Date

2020-10-30

Data di Scadenza
Expiration Date

2023-10-29

Settore IAF 14 - 29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Declaration of CE conformity

Avantor Performance Materials B.V. reg. no. 38013066 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histopathology located at:

Teugseweg 20
7418 AM Deventer
The Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T.Baker[®] label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III. The BeneSphera[™] 3 Part Diff Analyzer H32 is in compliance with IEC 61010, Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use.

The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self-registration.

This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.

January 6, 2015

Dr. J. Mittendorf
QA & RA Manager

J.T.Baker® product list for CE marked products

Product no.	Product	Pack size
Hematology Analyzer		
2983	BeneSphera™ 3-part Diff Hematology Analyzer H32	1 unit
Clinical Chemistry Analyzer		
2946	BeneSphera™ Clinical Chemistry Analyzer C72	1 unit
Diluents		
3961	Diluid 100 Plus	20 liter
2990.9010PC	Diluid™ 22	10 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9020	Diluid Abacus	20 liter
3430.9010	Diluid Abacus	10 liter
3996	Diluid AC 900	20 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
2901.9010PC	Diluid BS34	10 liter
3963	Diluid III Diff	20 liter
3963.9010	Diluid III Diff	10 liter
3459.9020	Diluid Erma	20 liter
3419.9020PC	Diluid M5	20 liter
3439.9020PC	Diluid Mindray	20 liter
3483.9020PC	Diluid NR	20 liter
2987.9020PC	Diluid Ruby	20 liter
3832.9020	Diluid/Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3495.9010PC	Sheath D	10 liter
3471.9020PC	Sheath Fluid 3000/3500	20 liter
Lyse		
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet 1000 CN free	5 liter
2986.0500PE	CyMet™ 22	500 ml
3469.9010PC	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3839.5000PC	CyMet 3500	5 liter
3825	CyMet 3500 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3417.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
2950.2500PE	CyMet ASA	2.5 liter
2951.0500PE	CyMet ASB	500 ml
2952.9010PC	CyMet AS CN Free	10 liter
3755	CyMet Automated	5 liter
2982.0500PE	CyMet BS3 CN free	500 ml
2902.1000PE	CyMet BS34 CN Free	1 liter
3968.0500	CyMet III Diff	500 ml
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3511.1000	CyMet III Diff CN free	1 liter
3511.5000	CyMet III Diff CN free	5 liter

3416.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3853.1000	CyMet H20	1 liter
3425.0500	CyMet KX CN Free	500 ml
2985.1000PE	CyMet LH 53	1 liter
3489.1000PE	CyMet MBA	1 liter
3418.1000PE	CyMet MD(I)	1 liter
2984.1000PE	CyMet MD(II) 53	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3497.0500PE	CyMet MH CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3863.1000	CyMet Micro CN free	1L micros
3441.0500PE	CyMet Mindray	500 ml
3440.0500PE	CyMet Mindray CN Free	500 ml
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
2988.5000PC	CyMet Ruby CN Free	5 liter
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3788	CyMet STX/STL	1 liter
3475.5000PC	LeucoLyse	5 liter
2989.5000PC	LeucoLyse Ruby	5 liter
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3513.1000PE	RBCLyse™	1 liter
3518G.1000PE	RBCLyse G	1 liter
3514.0500PE	WBCStabilise™	500 ml
Reticulocyte Reagents		
3493.1000PE	RetiClear™ MHG	1 liter
3774	RetiCount™	30 ml
2953.0210PE	RetiCount AS	210 ml
3777	RetiCount CD	15 x 3.5 ml
3494.0200PE	RetiCount G	200 ml
Cleaners		
3507.9020	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3763	DetectoTerge™	5 liter
3766	DetectoTerge	1 liter
2970.0900PE	DetectoTerge BS	900 ml
3917	HypoChlorite	5 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3432.1000PE	ProClean Abacus	1 liter
3432.5000	ProClean Abacus	5 liter
3902.0100PE	ProClean CD	100 ml
3862.9020PC	ProClean Extra	20 liter
3862.5000	ProClean Extra	5 liter
3862.1000	ProClean Extra	1 liter
3867.1000PE	ProClean Extra	1L micros
3498.1000PE	ProClean MX5	1 liter
3901	ProClean Plus	100 ml
3442.5000PE	Rinse Mindray	5 liter

Product no.	Product	Pack size
Reagent Packs		
2910	Reagent Pack BS34	1 pack
Hematology Controls and Calibrators		
3427/3428/3429	8-Parameter Control L/N/H	2.5 ml
3463/3464/3465	8-Parameter Control L/N/H	2.5 ml
3701/3702/3703	8-Parameter Control L/N/H	4.5 ml
3746	8-Parameter Control L+N+H	3 x 2.5 ml
3747	8-Parameter Control 4xN	4 x 2.5 ml
3751	8-Parameter Control 1xL+4xN+1xH	6 x 2.5 ml
3633/3634/3635	8-Parameter Control ext L/N/H	2.5 ml
3433/3434/3435	3-Diff Control L/N/H	2.5 ml
3502/3503/3504	3-Diff Control L/N/H	4.5 ml
3466	3-Diff Control 4xL	4 x 2.5 ml
3467	3-Diff Control 4xN	4 x 2.5 ml
3468	3-Diff Control 4xH	4 x 2.5 ml
3421/3422/3423	3-Diff Control ext L/N/H	2.5 ml
3681/3682/3683	5D Control L/N/H	5.0 ml
3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3613/3614/3615	BC-Diff 5 Control L/N/H	4.5 ml
3940	Cal Set 1	2 x 2.5 ml
3452/3453/3454	CD-Diff Control L/N/H	3.0 ml
3838	CD-Diff Control 2xL+2xN+2xH	6 x 3.0 ml
3455/3456/3457	K-Diff Control L/N/H	2.5 ml
3424	Platelet Control Ext. value	5 x 3 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3652/3653/3654	XE-RE'T Control L/N/H	3.0 ml

Product no.	Product	Pack size
Stains and Dyes		
3800.1000PE	Eosin-Y Alcoholic	1 liter
3800.2500PE	Eosin-Y Alcoholic	2.5 liter
3800.9200	Eosin-Y Alcoholic	200 liter
3446.1000PE	Eosin Y 0.5% Aqueous	1 liter
3446.9200	Eosin Y 0.5% Aqueous	200 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3856.9180ST	Giemsa	180 liter
3870.1000	Hematoxyline (Mayer)	1 liter
3870.2500	Hematoxyline (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3873.9200	Hematoxyline (Harris, Gill II)	200 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	500 ml
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
Clearing agent		
3905.2500PE	UltraClear™	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
Mounting media		
3921.0500	UltraKitt™	500 ml
3921.0600	UltraKitt	6 x 100 ml
3921.9025ST	UltraKit	25 liter
3882.0500	Mounting Medium High	500 ml
3883.0500	Mounting Medium Low	500 ml
Fixatives		
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010PE	10% v/v Buffered Formaldehyde	10 liter
3933.9020	10% v/v Buffered Formaldehyde	20 liter
3933.9200	10% v/v Buffered Formaldehyde	200 liter
3880.1000	Bouin's Fixative	1 liter
3869.1200	Cervix Fixative	12 x 125 ml
3884.9010PC	Cytology Fixative LBCM	10 liter
3409.9010	Immuno PBS 20x concentrated	10 liter
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter



global assurance

This is to certify that the Quality Management System of:

Avantor Fluid Handling B.V.

Maidstone 50
5026 SK Tilburg
The Netherlands

applicable to:

The design, engineering, manufacturing and distribution of Single Use Systems and supporting hardware, including installation-, service- and maintenance activities for the pharmaceutical and biotech industry.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

A handwritten signature in black ink, appearing to read 'M. S. J.', is positioned over the large, faint 'nqa' watermark in the background.

For and on behalf of NQA, USA



Certificate Number: 16880
EAC Code: 34
Certified Since: March 22, 2012
Valid Until: March 19, 2024
Reissued: March 20, 2021
Cycle Issued: March 20, 2021

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

has been assessed by Intertek as conforming to the requirements of:

ISO 13485:2016

The quality management system is applicable to:

The design, development, manufacture, distribution, installation and service of IVDD General Laboratory Instruments.

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:

9362-8

Initial Certification Date:

March 28, 2012

Date of Certification Decision:

March 24, 2021

Issuing Date:

March 27, 2021

Valid Until:

March 27, 2024



Intertek



A handwritten signature in black ink, appearing to read "Calin Moldovean".

Calin Moldovean
President

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T 3J1,
Canada



EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / **BOEN HEALTHCARE CO., LTD**
Name and address of the manufacturer: / **Unit 602, International Center, No.535, Shenxu Road,**
Nom et adresse du fabricant: / **Suzhou, 215021, Jiangsu, China**
Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **Gilson Pipette Tips**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B
dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / **Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /**
Conformity assessment procedure: / **EG Annex III (expect point 6) of IVDD 98/79/EC**
Procédure d'évaluation de la conformité: / **Annexe III (sauf le point 6) de l'IVDD 98/79 / CE**
Procedura di valutazione della conformità: **Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 201.05.26

Ort, Datum / Place, date /
Lieu, date / Luogo, data

General Manager

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione



EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / **BOEN HEALTHCARE CO., LTD**
Name and address of the manufacturer: / **Unit 602, International Center, No.535, Shenxu Road,**
Nom et adresse du fabricant: / **Suzhou, 215021, Jiangsu, China**
Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **Vacuum Blood Collection Tube**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B
dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / **Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /**
Conformity assessment procedure: / **EG Annex III (expect point 6) of IVDD 98/79/EC**
Procédure d'évaluation de la conformité: / **Annexe III (sauf le point 6) de l'IVDD 98/79 / CE**
Procedura di valutazione della conformità: **Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

CE

Suzhou, 201.05.26

Ort, Datum / Place, date /
Lieu, date / Luogo, data

General Manager

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione



**ERMA INC.**

2-31-6 Yushima, Bunkyo-ku, Tokyo 113-0034; Japan
Phone: 81-3-3818-6281 Fax: 81-3-3813-7301
E-mail address: trade@erma.co.jp

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model number	Catalog number
Full Automatic Blood Cell Counter	PCE-210N	01-210-0
Full Automatic Blood Cell Counter	PCE-210	01-210-2
PARTICLE COUNTER	PCE-210N	01-210-3
PARTICLE COUNTER	PCE-210	01-210-4
HEMATOLOGY ANALYZER	PCE-210N	01-210-5
HEMATOLOGY ANALYZER	PCE-210	01-210-6
Fully Automatic Blood Cell Counter	PCE-210	01-210-7

MANUFACTURER		
Name of company	Address	Representative
ERMA INC.	2-31-6 Yushima, Bunkyo-ku, Tokyo 113-0034, Japan	Yutaka Namiki Technical Manager, International Div.

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone / e-mail
Emergo Europe	Molenstraat 15 2513 BH, The Hague The Netherlands	+31-70-345-8570 Phone +31-70-346-7229 Fax service@emergogroup.com

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class: Self-Certify	Annex III of IVDD 98/79 EC Council Directive	Optional

ERMA INC. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In Vitro Diagnostic Medical Devices.

COMPANY REPRESENTATIVE: Hiroshi Shimosaka

TITLE: President

DATE: 08/24/2007

SIGNATURE: 



CE Registration Certificate

This is to certify that, in accordance with the In Vitro Diagnostic Medical Device Directive 98/79/EC, Emergo Europe agrees to perform all duties and responsibilities as the Authorized Representative for

ERMA Inc.
2-31-6 Yushima, Bunkyo-ku
Tokyo, 113-0034
Japan

as stipulated and demanded by the aforementioned Directive. The Dutch Competent Authorities have received the In Vitro Diagnostic Medical Device Registrations on the following dates:

21 September 2007
See attached product listing

Emergo Europe Registration Number: NL/CA01/601529

The Manufacturer has provided Emergo Europe with the appropriate Declaration(s) of Conformity confirming that the In Vitro Diagnostic Medical Devices fulfill the applicable requirements of Directive 98/79/EC.

25 September 2007



Rene van de Zande
President & CEO
Emergo Europe

[illegible]



Certificate JP06/040143

The management system of

ERMA INC.

3-4-8 Kiuri, Yoshikawa-shi, Saitama-ken, 342-0045 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016



For the following activities

1. Manufacture and service of blood cell counters, spectrophotometric analyzers for IVD use and bilirubin analyzers
2. Distribution of in-vitro diagnostic products for hemoglobin measurement

This certificate is valid from 16 November 2021 until 16 November 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date Issue 10. Certified since 16 November 2006

Authorised by



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SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 2016 0421

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