МЕДИКЛОН ®

ООО "Медиклон"

127276 Москва, Ботаническая ул. 35, т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-А во флаконах по 10 мл с красными крышками

Серия: 097312 **Единица:** 100 мл

Изготовлен: 16.12.2019 **Количество единиц** 60

Годен до: 16.12.2021 **Объем серии:** 10000 мл.

Паспорт: А097312 от 16.12.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	 Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует Соответствует Соответствует
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1:64 Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1:64 и В(III) 1:64	Соответствует 1:32 - 1:64 Соответствует 1:64 Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая
ОТК ООО «Медиклон» К.В. Ющенко

МЕДИКЛОН ®

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф (495) 231-2272 (499) 502-1214

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-Kell Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-Kell Супер

Серия: 197312 **Единица:** 100 мл

Изготовлен: 23.12.2019 **Количество единиц** 10

Годен до: 23.12.2021 **Объем серии:** 10000 мл.

Паспорт: К197312 от 23.12.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1.Внешний вид	Прозрачная желтоватая или розоватая жидкость	Соответствует
2. Серологические свойства 2.1 Специфичность 2.2 Гемагглютинирующая способность	Цоликлон Анти-Kell супер не должен агглютинировать эритроциты К(-) Четкая реакция агглютинации на плоскости должна наступать в течение 30 сек. после смешивания	Соответствует Соответствует
2.2 Активность	Титр Цоликлона Анти-Kell Супер в реакции прямой агглютинации в микроплате не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009
Заведующая ОТК ООО «Медиклон» М.С.Орлова

МЕДИКЛОН®

ООО "Медиклон"

127276 Москва, Ботаническая ул. 35, т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-АВ

Серия: 099812 **Единица:** 100 мл

Изготовлен: 23.12.2019 **Количество единиц** 10

Годен до: 23.12.2021 **Объем серии:** 10000 мл.

Паспорт: АВ09812 от 23.12.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует Соответствует Соответствует
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1:64 Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1:64 и В(III) 1:64	Соответствует 1:32 - 1:64 Соответствует 1:64 Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» К.В. Ющенко

МЕДИКЛОН®

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35, т\ф (495) 231-2272 (499) 502-1214

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-D Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D Супер во флаконах по 10 мл с зелеными крышками

Серия: 294712 **Единица:** 100 мл

Изготовлен: 23.12.2019 **Количество единиц** 60

Годен до: 23.12.2021 **Объем серии:** 10000 мл.

Паспорт: Дс294712 от 23.12.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон Анти-D Супер не должен агглютинировать D(–) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступать в течение 30 сек. после смешивания реагента с D(+) эритроцитами	Соответствует 30 сек.
2.3 Титр	Титр Цоликлона Анти-D Супер в реакции агглютинации на плоскости с D(+) эритроцитами 1:32 Титр Цоликлона Анти-D Супер в реакции прямой агглютинации с D(+) эритроци-тами в микроплате не ниже 1:256	Соответствует 1:32 1:256

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

МЕДИКЛОН®

ООО "Медиклон"

127276 Москва, Ботаническая ул. 35, т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-В во флаконах по 10 мл с синими крышками

Серия: 097412 **Единица:** 100 мл

Изготовлен: 16.12.2019 **Количество единиц** 60

Годен до: 16.12.2021 **Объем серии:** 10000 мл.

Паспорт: В097412 от 16.12.2019

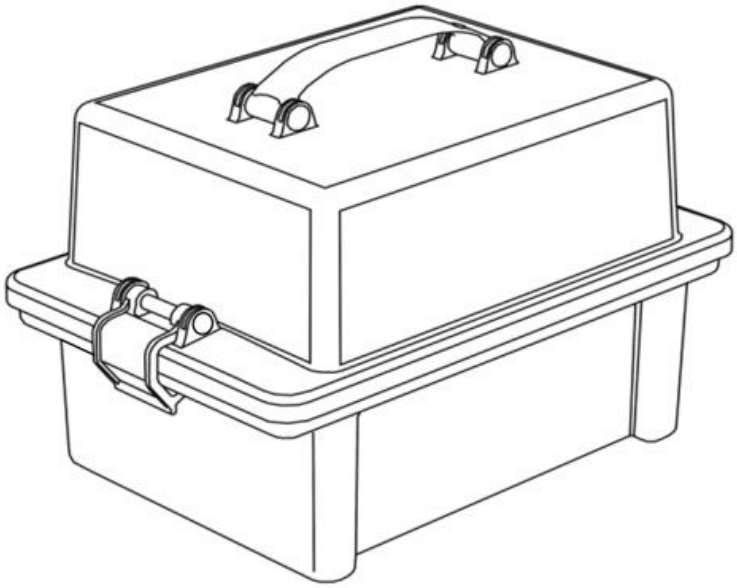
Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.2 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64	Соответствует 1:32 - 1:64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1:64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1:64 и В(III) 1:64	Соответствует 1:32 - 1:64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая
ОТК ООО «Медиклон» К.В. Ющенко

КОМПАНИЯ ЕЛАМЕД

Руководство по эксплуатации
ГИКС.942819.102 РЭ



Укладка-контейнер для транспортировки пробирок и других малогабаритных изделий медицинского назначения УКТП-01 «ЕЛАТ» по ГИКС.942819.102 ТУ

Настоящее руководство по эксплуатации (РЭ) является эксплуатационным документом на «Укладку-контейнер для транспортировки пробирок и других малогабаритных изделий медицинского назначения УКТП-01 «ЕЛАТ» по ГИКС.942819.102 ТУ».

Перед началом эксплуатации необходимо изучить и при работе соблюдать все правила и рекомендации, приведенные в РЭ.

Специальной подготовки обслуживающего персонала не требуется.

При покупке необходимо проверить комплектность, отсутствие механических повреждений и убедиться, что в РЭ поставлены штамп ОТК, дата упаковки.

1. Описание и работа

1.1. Назначение

Изделие УКТП-01 «ЕЛАТ» предназначено для транспортировки пробирок и других малогабаритных изделий медицинского назначения в медицинских организациях.

Изделие поставляется в двух вариантах исполнения.

1.2. Условия эксплуатации

1.2.1. Изделие УКТП-01 «ЕЛАТ» эксплуатируется в следующих условиях:

- температура окружающего воздуха от плюс 10 °С до плюс 35 °С;
- влажность окружающего воздуха, при температуре плюс 25 °С, не более 80%;
- атмосферное давление от 84 до 106,7 кПа (630 - 800 мм рт. ст.).

1.3. Основные параметры

1.3.1. Габаритные размеры укладки-контейнера, мм - (340х217,5х261)±3%.

1.3.2. Масса укладки-контейнера, не более - 2,0 кг.

1.3.3. Максимальная рабочая нагрузка, не более - 6,0 кг.

1.3.4. Максимальное количество переносимых одновременно пробирок:

- вариант 1 - 40 шт.
- вариант 2 - 80 шт.

Отверстия в подставке рассчитаны на размещение пробирок диаметром не более 16,9 мм, высотой от 100 до 210 мм.

1.4. Характеристики

1.4.1. Укладка-контейнер устойчива к воздействию температуры не более 50 °С.

1.4.2. Наружные и внутренние поверхности укладки-контейнера устойчивы к дезинфекции химическим методом по МУ 287-113: 3% раствором перекиси водорода по ГОСТ 177 с добавлением 0,5% моющего средства типа «Лотос» по ГОСТ 25644 и 1% раствором хлорамина по ТУ9392-031-00203306.

1.4.3. Календарный срок службы укладки-контейнера должен быть не менее 2 лет с даты начала эксплуатации до достижения предельного состояния.

Критерием предельного состояния укладки-контейнера является наличие трещин, раковин, вздутий, расслоений.

FOERSTER FORCEPS 20 cm

Code:	**26800**
Category:	**GYN instruments**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**142439**
CND:	**L05090399**
EAN13:	**8023279268003**

Description: **Stainless Steel dressing sponge holding Foerster forceps - 20 cm**

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) – Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DICHIARAZIONE DI CONFORMITA'/*DECLARATION OF CONFORMITY*

La Società GIMA S.p.A., con sede operativa in Gessate (MI), in Via Marconi 1, e sede legale in Milano, in Via Tommaso Grossi 2, in qualità di fabbricante del dispositivo medico:
We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Dispositivo medico / *Medical Device*	**Codice/Code**
PINZA FOERSTER - 20 cm *FOERSTER FORCEPS 20 cm*	26800

Classe di rischio I (Non Sterile), in accordo all'Allegato IX della Direttiva 93/42/CEE e ss.mm.ii., (recepita in Italia con D.lgs 46/97, e ss.mm.ii.), dichiara, sotto la propria esclusiva responsabilità, che tale dispositivo:
Risk class I (Not Sterile), according to the Annex IX, Directive 93/42/EEC and further amendments (enforced in Italy by Leg. Decree No. 46/97 and further amendments), declares, under its own responsibility, that this medical device:

- è conforme ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii., come da fascicolo tecnico conservato in Azienda;
  comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as per the Technical Documentation filed in the Company;
- è fabbricato in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato VII della sopra citata direttiva.
  is manufactured according to the Quality System which satisfies requirements of the Annex VII of the above mentioned directive.

Gessate, 4/1/2020

GIMA S.p.A.
Il legale Rappresentante
The legal Representative
(Nicola Manzoni)

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) – Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DICHIARAZIONE/*DECLARATION*

La Società GIMA S.p.A., con sede operativa in Gessate (MI), in Via Marconi 1, e sede legale in Milano, in Via Tommaso Grossi 2, in qualità di fabbricante del dispositivo medico:
We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

Dispositivo medico / *Medical Device*	**Codice/Code**
PINZA FOERSTER - 20 cm *FOERSTER FORCEPS 20 cm*	26800

dichiara, sotto la propria esclusiva responsabilità, che tale dispositivo è conforme alla Direttiva 93/42/CEE e ss.mm.ii. **e che, in accordo alla MDCG 2020-2, sarà reso conforme al Regolamento (UE) 2017/745 per cambio classe entro maggio 2024.**
declares, under its own responsibility, that this medical device comply with Directive 93/42/EEC and further amendments ***and that, in accordance with MDCG 2020-2, will be made compliant with the Regulation (EU) 2017/745 for class change by May 2024.***

Gessate, 4/1/2020

GIMA S.p.A.
Il legale Rappresentante
The legal Representative
(Nicola Manzoni)

S/S KIDNEY DISH - deep - 207x98x39 mm

Code:	**26581**
Category:	**Stainless steel holloware**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**1925317**
CND:	**V0402**
EAN13:	**8023279265811**

Description:

Stainless Steel AISI 304 holloware with thickness 0.6 mm.

Kidney dish 18/8 - deep - tray 8"

Technical Specifications:

- **Size: 207 x 98 x 39 mm**
- **Capacity: 400 ml**
- **Autoclavable 121°C**
- **AISI 304**

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

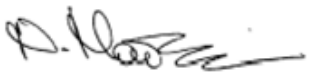
Medical Device (Trade Name and description)	**Code**	**Basic UDI-DI code**
S/S KIDNEY DISH - deep - 207x98x39 mm	26581	80232790000V04020400010RT

Risk class I (Not sterile), according to the Rule 1 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;

Gessate, 5/28/2021

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)



LABORATORY TRAY 375x300x75 mm - plastic

Code:	**37715**
Category:	**Plastic and cardboard holloware**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**1657440**
CND:	**V0899**
EAN13:	**8023279377156**

Description:

LABORATORY TRAY 375 x 300 x 75 mm

Economic line of reusable plasticware products.
Made in polypropylene, easy to clean and resistant to most healtcare chemicals.

Autoclavable at 121°C (15 min), 126°C (10 min) or 134°C (3 min).

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

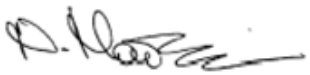
Medical Device (Trade Name and description)	**Code**	**Basic UDI-DI code**
LABORATORY TRAY 375x300x75 mm - plastic	37715	80232790000V08996400030BJ

Risk class I (Not sterile), according to the Rule 1 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;

Gessate, 5/28/2021

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)



Certificate ES16/20725

The management system of

DELTALAB GROUP

DELTALAB, S.L., KEYLAB, S.L.U., NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.

Pol. Ind. La Llana
Plaza de la Verneda, 1
08191 Rubí, Barcelona

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis, general labware, containers and healthcare products. Manufacture and commercialization of consumables for the laboratory. Commercialization and distribution of equipment for the storage of prepared samples, cryogenic stored samples, syringes, general labware and industrial packages. Commercialization and distribution of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes. Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.

This certificate is valid from
11 October 2019 until 11 October 2022.
Issue 4. Company certified since October 2010.
Certified with SGS since 11 October 2016.

This is a multisite certification. See following page(s).

Authorised by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29 28042 Madrid España
t 3491 313 8115 f 34 91 313 8102 www.sgs.com

Certificate ES16/20725

DELTALAB GROUP

DELTALAB, S.L., KEYLAB, S.L.U., NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.

ISO 9001:2015

Issue 4

Sites where these activities are totally or partially carried out

DELTALAB, S.L.
Pol. Ind. La Llana, Plaza de la Verneda, 1 – 08191 Rubí, Barcelona (España)

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.
Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

KEYLAB, S.L.U.
Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.
Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

NIRCO, S.L.
Pol. Ind. Expansión, Puerto de Navafría, 12 - 28935 Móstoles -Madrid (España)
Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)

Manufacture and commercialization of consumables for the laboratory.
Commercialization and distribution of diagnostic kits
Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.

ENVASES FARMACÉUTICOS, S.A.
C/ Paralela, 15 - 28860 Paracuellos de Jarama (Madrid)

Design, manufacture and commercialization of laboratory material for the collection, transport and conservation of samples for analysis, laboratory material for general use, containers and products for personal care
Commercialisation and distribution of laboratory material for general use, products and equipment for personal care, syringes and cosmetic products.

Certificate ES16/20725.01

DELTALAB, S.L.

Pol. Ind. La Llana
Plaza de la Verneda, 1
08191 Rubí, Barcelona

has been assessed as part of the management system of DELTALAB GROUP certified organization as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, hematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages. Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

in / from the following sites

Pol. Ind. La Llana, Plaza de la Verneda, 1 - 08191 Rubi (Barcelona)

Valid from
11 October 2019 until 11 October 2022.
Issue 1.

This document Is part of Certificate ES16/20725.
The validity of this document is subject to the certificate.

Nº 05 / C - SC001

Authorized by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

Sterile swab in round tube

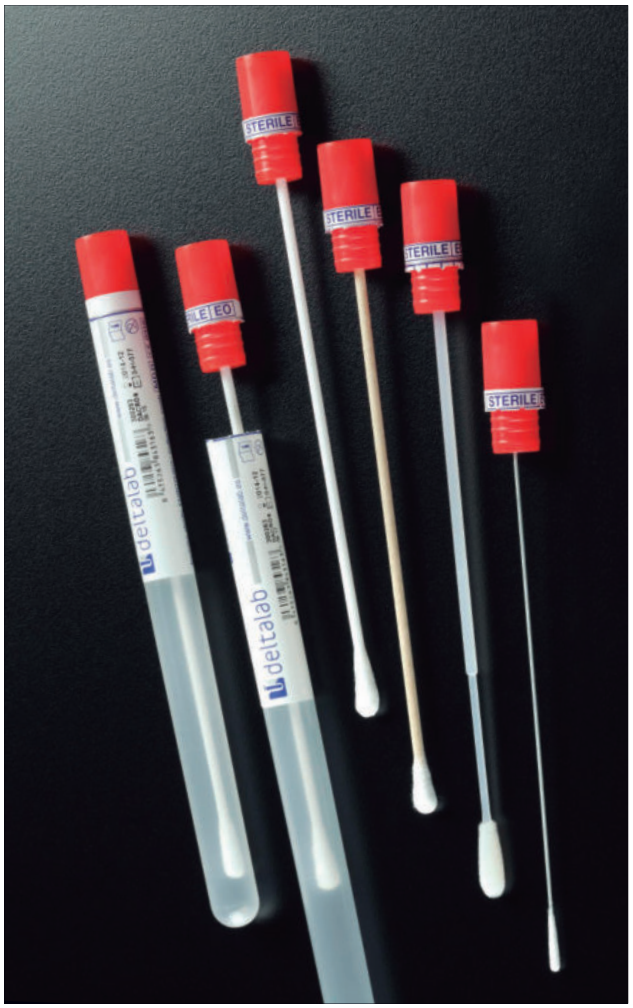
Sterile dry swabs supplied in shockproof round bottom polypropylene tube, with a label sealing the cap.
Dimensions of tube: Ø 13 x 165 mm.
Sterilised by ethylene oxide.

code	shaft material	tip material	case quantity	case weight	case volume	cases per pallet
300250	wood	cotton	4 x 500	14.00	0.060	24
300250.1	wood	pure cotton	4 x 500	14.00	0.070	24
300261	snappable PS	cotton	4 x 500	14.90	0.070	24
300252	snappable PS	viscose	4 x 500	15.00	0.066	24
300263	snappable PS	poliéster	4 x 500	15.00	0.062	24
300251	aluminium	cotton	4 x 500	15.00	0.066	24
300253	aluminium	viscose	4 x 500	13.90	0.070	24
300265*	PS	flocked polyester	4 x 500	14.20	0.065	24

Expiry date: 48 month from sterilization date.
"Code not available for sale in Italy, UK and Ireland. Class I Sterile product"

CE MD Class IIa

Flocked polyester: material with high absorbency and overall sample elution.



Human DNAsa, RNAsa and DNA free certified swabs, steriles

Human DNA free Certified. **Sterilised by ethylene oxyde**.
The swab is supplied in a polypropylene tube, which protects the sample up to the laboratory prior to its analysis. The stick of the swab is made of polystyrene while the head is produced with viscose or polyester according to the code. The tube is labeled indicating code, description, lot, expiry date and providing an identifying area to note down collection details (site, date, etc.). Moreover, the label seals the tube with the cap of the swab, acting like a tamper evident system.

code	shaft material	tip material	selling unit	case quantity	case weight	case volume
300252DNA	polystyrene	viscose	500	4 x 500	14.20	0.070

Expiry date: 48 months from sterilisation date

DNAse RNAse FREE

This product is not considered a medical device and does not carry CE marking because it is not for a subsequent diagnosis of a pathology, but is designed for saliva sampling, for genetic analysis (identification of human DNA) within the scope of the investigation and the forensic market.

SPARE FILTER for Clinic, SuperVega trolley - connector 11 mm

Code:	**28239**
Category:	**Filtres**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**II A**
NSIS:	**1281843**
CND:	**A0680**
EAN13:	**8023279282399**

Description:

Hydrophobic, antibacterial filter
Compatible with: SuperVega on trolley, Clinic, Clinic Plus

SCISSORS STRAIGHT SHARP/SHARP - 16 cm

Code:	**26893**
Category:	**Scissors**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**1758611**
CND:	**L010499**
EAN13:	**8023279268935**

Description: **STAINLESS STEEL SURGICAL SCISSORS.**

Instructions: GB, FR, IT, ES, PT, DE, GR, Arabic.

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

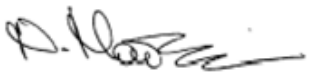
Medical Device (Trade Name and description)	**Code**	**Basic UDI-DI code**
SCISSORS STRAIGHT SHARP/SHARP - 16 cm	26893	802327900L0104990000000VD

Risk class I (Not sterile), according to the Rule 1 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;

Gessate, 5/28/2021

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)



3540	375	Latex free, without rim

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*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	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

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

CERTIFICATO CE

Certificato n. 1976/MDD

Dichiarazione di approvazione del sistema qualità

(Garanzia di qualità della produzione)

Visto l'esito delle verifiche condotte in conformità all'Allegato V, punto 3 e tenendo conto dell'Allegato VII, punto 5 della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

mantiene negli stabilimenti di:

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Carte per registrazione ad uso medico

Modd. come da documento allegato "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valido solo se provvisto di timbro IMQ.
Marca Ceracarta

ai requisiti metrologici ad essi applicabili della direttiva suddetta (in tutte le fasi della fabbricazione) ed è sottoposta alla sorveglianza prevista dal punto 4 dell'Allegato V.

Riferimento pratiche IMQ:
DM17-0017248-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 2017-11-18

Data Scadenza: 2022-11-17

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici in base alla direttiva 93/42/CEE".

EC CERTIFICATE

Certificate No 1976/MDD

Production Quality Assurance System Approval Certificate

On the basis of our assessment carried out according to Annex V, section 3 and considering the Annex VII, section 5 of the Directive 93/42/EEC and its revised version, we hereby certify that:

CERACARTA SPA

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

manages in the factories of:

47122 FORLI' (FC) - VIA SECONDO CASADEI 14 Z.I. VILLA SELVA (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Electromedical recording chart paper

Type ref. as to annexed document "ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017"; valid only if provided with IMQ stamp.
Trade mark Ceracarta

with the relevant metrological requirements of the aforementioned directive (as far as all the manufacturing stage is concerned) and it is subject to surveillance as specified in section 4 of Annex V.

Reference to IMQ files Nos:
DM17-0017248-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date: 2017-11-18

Expiry Date: 2022-11-17

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

CERACARTA® S.p.A.

Carte diagrammate per tutte le apparecchiature di elettrodiagnostica.
Materiale di consumo ed accessori elettromedicali.
Carte per apparecchi registratori industriali.
Rotoli e pacchi speciali per sistemi esattoriali, di controllo, lotterie.
Etichette radiofrequenza e soluzioni integrate.

Chart Papers for all electrodiagnostic equipment
Disposable and electromedical accessories.
Chart Papers industrial recording instruments.
Special rolls and fanfolds for tickets checking sys
lottery.
Rfid labels and chain solutions.

Sede (Head office and works) :
Via Secondo Casadei, 14 - 47122 FORLI' – ITALY
Tel : 0039 0543 780055 • Fax : 0039 0543 781404
http : // www.ceracarta.it • e-mail : info@ceracarta.it.
Capitale Sociale : € 1.000.000 int. vers.
Registro Imprese FORLI'-CESENA
P.I. / C.F. / VAT.N. IT 00136740404
R.E.A. FORLI' N. 72646 – N. MECC. FO 006863

ELENCO CARTE DIAGRAMMATE CLASSE I F.M. REV.15 - 16/10/2017

Codice famiglia identificativo	Descrizione famiglia
22.01	Pacchi stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
21.01	Rotoli stampati medicali (per ECG,EEG,CTG,e laboratorio analisi)
32.01	Schede e dischi stampati medicali

2017-11-18

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
24.01.2020

CODICE ARTICOLO: / *ITEM CODE:* **12660**

DESCRIZIONE / *DESCRIPTION*

Bicchierini graduati, in polipropilene, adatti all'erogazione di farmaci liquidi e secchi.
Graduazioni espresse sia in cc che in ml.
Volume 30 ml.

Polypropylene cups, suitable for dispensing liquid and dry medications.
Graduations indicated in cc and ml.
Volume 30 ml.

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / *NOT STERILE***	*Microbiological status*
Materiale impiegato	POLIPROPILENE / *POLYPROPYLENE*	*Raw material*
Colore	NEUTRO / *NEUTRAL*	*Colour*
Dimensioni (mm)	Ø 45 X 37 MM	*Dimensions (mm)*
Scala graduata (cc – mm)	2,5 - 5 – 7,5 – 10 – 15 – 20 – 25 - 30	*Graduated scale (cc – mm)*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione d'uso è per "USI GENERALI DI LABORATORIO", bicchierino porta medicine
Il dispositivo in oggetto NON è soggetto a certificazione CE ed è destinato esclusivamente ad uso professionale.

Intended purpose is "GENERAL LABORATORY USE", cups for medicine.
PRODUCT NOT SUBJECT TO CE MARKING.
For professional use only

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +50°C
Store in dry place, Temperature range: min -10°C max +50°C

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substance check the resistance / compatibility chart on our catalogue

IMBALLO / *PACKING*

Quantità (pz): *Quantity (pcs):*	1.000	Confezione interna (pz): *Internal packing (pcs):*	500	QUANTITÀ MINIMA VENDIBILE *MINIMUM SALEABLE QUANTITY*	
Misura esterna scatola (cm): *External box dimensions (cm):*	29,3 x 17,5 x 24	Peso (Kg): *Weight (Kg):*	2,3	Volume (m^3): *Volume (m^3):*	0,012

SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS*


Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
01.12.2020

MADE IN ITALY

ARTICOLO: **CONTENITORI FORMA ROTONDA**
ITEM: **ROUND SHAPE CONTAINERS**

DESCRIZIONE / *DESCRIPTION*

CONTENITORE PER RIFIUTI SPECIALI FORMA ROTONDA
Questa serie si compone di sette misure di contenitori monouso e resistenti alla perforazione a forma rotonda per lo smaltimento di rifiuti acuminati, taglienti, pungenti e affilati. La forma conica e le tacche sul coperchio agevolano lo smaltimento e la rimozione degli aghi, mentre le alette antideflusso sul coperchio impediscono la fuoriuscita dei rifiuti. Tutti i modelli sono provvisti di chiusura provvisoria e definitiva e dotati di manico solido; i tre modelli più capienti sono dotati di manico ergonomico per un utilizzo più agevole.

SAFETY CONTAINERS ROUND SHAPE
This line includes round shape disposable and puncture resistant containers for the disposal of sharp and cutting waste and it comes in sever sizes.
The conical shape and the indent on the lid ease the disposal and the remove of needles, whilst the anti-defluxion flow wings on the lid prevent the outflow of the waste. All the models have temporary and definite closure and are fitted with solid handle; the three most volumious models are fitted with an ergonomic handle that eases use.

MATERIALE / *RAW MATERIAL*

Materiale plastico ecologico (Polipropilene copolimero colorato conforme alla normativa REACH con colorante senza cadmio). Il corpo del contenitore è di colore giallo e il coperchio di colore rosso per consentirne l'immediata individuazione ed avvertire della pericolosità del contenuto.

Ecological plastic material (colored copolymer polypropylene compliant to REACH regulations and with masterbatch heavy metal free and cadmium free). The container body is yellow and the lid is red to allow the immediate detection and warning of the dangers of the content.

CERTIFICAZIONI / *CERTIFICATIONS*

Conformi alla Norma AFNOR NF X-30-511
Conforme Marchio NF
Conformi alla Norma ISO ISO 23907-1 - Kite Mark
Conformi all'accordo ADR - Certificato UN
Conforme FDA K071517
Conforme TRBA 250

Compliant to AFNOR NF X-30-511
Compliant to NF Mark
Compliant to ISO 23907-1 - Kite Mark
Compliant to ADR - UN Certificate
Compliant to FDA K071517
Compliant to TRBA 250

ISO 23907: 2012
KM 99113

NF CONTRÔLÉ PAR LNE

FDA K071517

TRBA 250

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

VANTAGGI / *ADVANTAGES*

- Manico ergonomico per i modelli più capienti
- Meccanismo di sgancio aghi da insulina
- Alette antideflusso per impedire la fuoriuscita dei rifiuti nei contenitori cod. 7015 – 7020 – 7050 – 7070 – 7120.
- Chiusura permanente irreversibile
- Indicazione del livello di riempimento massimo
- Disponibilità di supporti vari
- Nessuna emissione di gas nocivi in fase di incenerimento. Alla fine del ciclo vitale, i contenitori vengono smaltiti per incenerimento, senza emanazioni nocive e senza deposito di materiali pesanti
- Il contenitore può essere autoclavato a 134' per 18 minuti

- *Ergonomic handle for the more spacious models*
- *Machanism for unhooking insulin needles*
- *Anti-defluxion wings that prevent the outflow of the waste in containers cod. 7015 – 7020 – 7050 – 7070 – 7120.*
- *Irreversible permanent closure*
- *Maximum filling level indicator*
- *Various supports available*
- *No emission of any harmful gasses during the inceneration process. Once filled, the containers have to be disposed through incineration, releasing no toxic emissions*
- *Suitable to autoclave at 134° for 18 min*

COD. 7006

Modello concepito per le postazioni a debole produzione di rifiuti (vassoio di cura, carrello, gabinetto del medico, domicilio del paziente, ecc.)
Item designed for low volumes of waste (care tray, trolley, domestic care, doctor's office, etc.)

DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
Ø100 x 145 mm H	
SPESSORE	***THICNESS***
1,9 mm	
FORMA	***SHAPE***
Tronco di cono / *Truncated cone*	
PESO	**WEIGHT**
87 gr.	
CARICO MASSIMO	**MAXIMUM LOAD**
0,4 Kg.	
CAPACITÀ NOMINALE	**NOMINAL VOLUME**
0,60 Lt.	
CAPACITÀ EFFETTIVA	**EFFECTIVE VOLUME**
0,67 Lt.	
CAPACITÀ UTILE	**USEFUL VOLUME**
0,536 Lt.	

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

COD. 7008

Modello concepito per le postazioni a debole produzione di rifiuti (vassoio di cura, carrello, gabinetto del medico, domicilio del paziente, ecc.)
Item designed for low volumes of waste (care tray, trolley, domestic care, doctor's office, etc.)

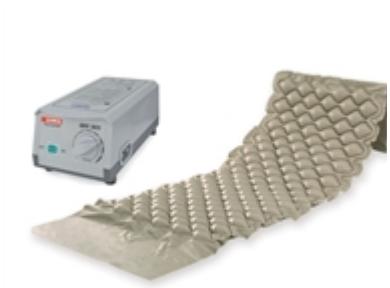
DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
Ø100 x 184 mm H	
SPESSORE	*THICNESS*
1,9 mm	
FORMA	*SHAPE*
Tronco di cono / *Truncated cone*	
PESO	WEIGHT
109 gr.	
CARICO MASSIMO	MAXIMUM LOAD
0,460 Kg.	
CAPACITÀ NOMINALE	NOMINAL VOLUME
0,80 Lt.	
CAPACITÀ EFFETTIVA	EFFECTIVE VOLUME
0,81 Lt.	
CAPACITÀ UTILE	USEFUL VOLUME
0,652 Lt.	

COD. 7015

Modello di utilizzo corrente (Ospedale, Centro di cure, Clinica, ecc.)
Item designed for frequent use (Hospitals, Helthcare Centres, Clinics, etc.)

DIMENSIONI ESTERNE	*EXTERNAL DIMENSIONS*
Ø140 x 165 mm H	
SPESSORE	*THICNESS*
1,9 mm	
FORMA	*SHAPE*
Tronco di cono / *Truncated cone*	
PESO	WEIGHT
155 gr.	
CARICO MASSIMO	MAXIMUM LOAD
0,850 Kg.	
CAPACITÀ NOMINALE	NOMINAL VOLUME
1,50 Lt.	
CAPACITÀ EFFETTIVA	EFFECTIVE VOLUME
1,60 Lt.	
CAPACITÀ UTILE	USEFUL VOLUME
1,20 Lt.	

BUBBLE AIR MATTRESS + COMPRESSOR (28564+28565)



Code:	**28566**
Category:	**Intensive care anti-decubitus mattresses**
Unit of sale:	**1 kit**
Minimum order:	**1**
Type:	**Medical device**
Class:	**I**
NSIS:	**817830**
CND:	**Y033399**
EAN13:	**8023279285666**

Description:

• BUBBLE MATTRESS
Designed for the treatment and prevention of pressure sore stage I in short-term and domiciliary therapies. The PVC mattress is composed of 130 7 cm-high bubble cells, particularly comfortable. Fixable to bed by extra flaps on both top and bottom side. Cold-resistant -30 degrees.
Flaps length: 50+50 cm (top + bottom).

• PUMP SYSTEM
Special silent pump for an excellent pressure regulation by a knob on the front panel.
It can be hung to any kind of hospital bed frame by means of two adjustable hooks.
For use with bubble or alternating cell mattresses.

Technical Specifications:

Bubble mattress:
• Total size: 200 x 90 x 7 cm
• Cell height: 7 cm (2.7")
• Material: PVC
• Thickness: 0.32 mm
• Number of cells: 130
• Suitable for persons up to: 135 kg

Pump system:
• Size: 25 x 12 x h 10 cm
• Operating voltage: 220 V, 50 Hz
• Working pressure: 40-100 mmHg
• Air output: 6-7 liter/min
• Cycle time: 6 min
• Plastic casing: Taiwan chimei ABS
• TUV-CE IEC/EN60601-1; 60601-1-2

GIMA S.p.A.
Via Marconi, 1
20060 Gessate (MI) –Italy
www.gimaitaly.com

ITALIAN DIVISION
gima@gimaitaly.com
EXPORT DIVISION
export@gimaitaly.com

DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

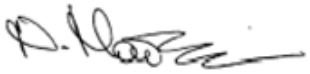
Medical Device (Trade Name and description)	**Code**	**Basic UDI-DI code**
BUBBLE AIR MATTRESS + COMPRESSOR (28564+28565)	28566	802327900Y0333998100000PW

Risk class I (Not sterile), according to the Rule 13 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;
- comply with directive 2011/65/EU (and subsequent amendments and integrations) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Gessate, 5/28/2021

GIMA S.p.A.
The legal Representative
(Nicola Manzoni)



DACRIL

Acid poliglicolic, fir multifilament, acoperit, resorbabil

Polyglycolic acid suture, multifilament, coated, absorbable

SUTURĂ CHIRURGICALĂ CU AC

SURGICAL SUTURES WITH NEEDLE — *REVERSE CUTTING*

DESCRIERE AC *Needle Description*	CARACTERISTICI FIR *Thread Characteristics*				MODALITATE DE AMBALARE *Packaging*		COD *Code*
	USP	EP	LUNGIME *Length* (cm)	CULOARE *Colour*	NR. DE SUTURI/ PLIC *No. of Threads / Pouch*	NR. DE PLICURI/ CUTIE *No. of Packs / Box*	
Ac 18.7 mm triunghiular 3/8 cerc *Needle 18.7 mm triangular 3/8 circle* 	5/0	1	75	violet	1	12	**BX1066**
	4/0	1.5	75	violet	1	12	**BX132**
	3/0	2	75	violet	1	12	**BX140**
	3/0	2	100	violet	1	12	**BX1119**
Ac 24.3 mm triunghiular 3/8 cerc *Needle 24.3 mm triangular 3/8 circle* 	3/0	2	75	violet	1	12	**BX104**
	3/0	2	75	necolorat/*undyed*	1	12	**BX104U**
	3/0	2	100	violet	1	12	**BX1099**
	3/0	2	120	violet	1	12	**BX1126**
	2/0	3	75	violet	1	12	**BX141**
	2/0	3	100	violet	1	12	**BX1120**
Ac 26 mm triunghiular 1/2 cerc *Needle 26 mm triangular 1/2 circle* 	3/0	2	75	violet	1	12	**BX1341**
Ac 29.7 mm triunghiular 3/8 cerc *Needle 29.7 mm triangular 3/8 circle* 	2/0	3	75	violet	1	12	**BX109**
	2/0	3	90	violet	1	12	**BX1257**
	2/0	3	100	violet	1	12	**BX1101**
	2/0	3	120	violet	1	12	**BX1128**
	0	3.5	75	violet	1	12	**BX1248**
	0	3.5	90	violet	1	12	**BX1053**
Ac 30 mm triunghiular 1/2 cerc *Needle 30 mm triangular 1/2 circle* 	2/0	3	90	violet	1	12	**BX1350**

EC Certificate
Full Quality Assurance System

Certificate No.:
13422-2018-CE-CZS-NA-PS Rev. 1.0

Project No.:
PRJC-575486-2017-PRC-CZE

Valid Until:
01 November 2023

This is to certify that the quality system of:

Biosintex S.R.L.
4 Vladiceasca Str.
077168 Snagov
Romania

For design, production and final product inspection/testing of:

Sterile surgical sutures

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 11 September 2019

NORWEGIAN ACCREDITATION

PROD 021
Notified Body No.: 2460

For: DNV GL Presafe AS

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **13422-2018-CE-CZS-NA-PS Rev 1.0**

Project No.: **PRJC-575486-2017-PRC-CZE**

Valid Until: **01 November 2023**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-11-01
1.0	**Change of product name**	**2019-09-11**

Products covered by this Certificate:

Product Description	Product Name	Class
Surgical suture with /without needle	**DACRIL**- Polyglycolic acid multifilament coated absorbable **DACRIL RAPID**- Polyglycolic acid multifilament coated fast absorbable **DACRIL 910** - Poly(glycolide-co-Lactide) (90/10) multifilament coated absorbable **PDO-x** - Polydioxanone monofilament absorbable **MONO-x** - Poly(glycolide-co-caprolactone) (75/25) monofilament absorbable **BIOPRO**- Polypropylene monofilament non-absorbable	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 13464-2018-CE-CZS-NA-PS

Sites covered by this certificate

Site Name	Address
BIOSINTEX S.R.L.	4 Vladiceasca Str., RO 077168, Snagov, Romania

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
13422-2018-CE-CZS-NA-PS Rev 1.0	**PRJC-575486-2017-PRC-CZE**	**01 November 2023**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

BIOPRO

Polipropilenă, fir monofilament, neresorbabil
Polypropylene suture, monofilament, non-absorbable

SUTURĂ CHIRURGICALĂ CU AC
SURGICAL SUTURES WITH NEEDLE

REVERSE CUTTING

DESCRIERE AC *Needle Description*	CARACTERISTICI FIR *Thread Characteristics*				MODALITATE DE AMBALARE *Packaging*		COD *Code*
	USP	EP	LUNGIME *Length* (cm)	CULOARE *Colour*	NR. DE SUTURI/ PLIC *No. of Threads / Pouch*	NR. DE PLICURI/ CUTIE *No. of Packs / Box*	
Ac 29.7 mm triunghiular 3/8 cerc *Needle 29.7 mm triangular 3/8 circle* 	2/0	3	75	albastru/*blue*	1	12	**BX312**
	2/0	3	90	albastru/*blue*	1	12	**BX364**
Ac 39.2 mm triunghiular 3/8 cerc *Needle 39.2 mm triangular 3/8 circle* 	2/0	3	75	albastru/*blue*	1	12	**BX362**
	0	3.5	75	albastru/*blue*	1	12	**BX360**
	1	4	75	albastru/*blue*	1	12	**BX343**
Ac 40 mm triunghiular 1/2 cerc *Needle 40 mm triangular 1/2 circle* 	0	3.5	75	albastru/*blue*	1	12	**BX311**
	1	4	75	albastru/*blue*	1	12	**BX351**
	1	4	100	albastru/*blue*	1	12	**BX3060**
	2	5	75	albastru/*blue*	1	12	**BX379**
Ac 60 mm triunghiular drept *Needle 60 mm triangular straight* 	3/0	2	70	albastru/*blue*	1	12	**BX378**
2 ace 65 mm triunghiular drept *2 needles 65 mm triangular straight* 	2/0	3	45	albastru/*blue*	1	12	**BX350**