



Organismo Notificato 0373
Notified Body 0373

Istituto Superiore di Sanità

Certificato n° **QPZ-1941-20**
Certificate no.

Addendum n° **01-20**
addendum no.

Data prima emissione **29.07.2020**
First issue date
Data di emissione corrente **06.08.2020**
Current issue date
Data di scadenza **26.05.2024**
Expiry date

GARANZIA DELLA QUALITA' DELLA PRODUZIONE

secondo l'Allegato V della Direttiva Europea 93/42/CEE e successive modifiche ed integrazioni
(recepita in Italia con il D.Lgs. n. 46 del 24.02.1997 e successive modifiche ed integrazioni)

PRODUCTION QUALITY ASSURANCE

according to Annex V of EC Directive 93/42/EEC and subsequent modifications and integrations
(transposed in Italy by the D.Lgs. n. 46 issued on 24.02.1997 and subsequent modifications and integrations)

**L'Istituto Superiore di Sanità,
Organismo Notificato 0373, certifica che
il sistema di garanzia della qualità della
produzione
attuato da**

*The Istituto Superiore di Sanità,
Notified Body 0373, certifies that
the production quality assurance
enforced by*

STS MEDICAL GROUP AD

Sede Legale/ Registered Office:

Industrial Area "Sokolovetz"- 2800 Sandanski - BULGARIA

Altre sedi del Fabbrikante /Other sites of the Manufacturer:

Sede Produttiva/ Production Site: Industrial Area "Sokolovetz"- 2800 Sandanski - Bulgaria

Sede Operativa/ Operative Office: Industrial Area "Sokolovetz"- 2800 Sandanski - Bulgaria

Sede Amministrativa/Administrative Office: Industrial Area "Sokolovetz"- 2800 Sandanski - Bulgaria

per il dispositivo/i

for the device(s)

*(vedi allegato tecnico/ see technical sheet)**

**è conforme ai requisiti applicabili della
Direttiva Europea 93/42/CEE e successive
modifiche ed integrazioni.**

*is in compliance with the applicable
requirements of Council Directive 93/42/EEC and
subsequent modifications and integrations.*

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

* L'allegato tecnico è parte integrante del presente Certificato
The technical sheet is an integral part of this Certificate.



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ALLEGATO TECNICO

TECHNICAL SHEET

Il Certificato n°
The Certificate no.

QPZ-1941-20

Addendum n°
addendum no.

01-20

di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe IIa (Class IIa)

Nome prodotto (Product name)	Codice (Code)
<i>Compresse pacchi da Kg. 1 peso netto non sterile</i> (famiglia M08)	2XXXX – 6XXXX ¹
<i>Compresse piegate con bordino americano in garza o tnt sterili e non sterili</i> (famiglia M15-16-17-26-27)	2XXXX – 4XXXX – 5XXXX – 6XXXX – 8XXXX ¹ CRXXXXX 23322-700125 700086-50430 700090-XXXXY ⁴
<i>Garza in pacco in sterile</i>	30XXX
<i>Laparatomiche in garza prelavate and non pre-washed sterili e non sterili</i> (famiglia M13)	5XXXX – 6XXXX ¹ TXXXXXXXXXX CRXXXXX, 500-XXX 625105K, 625106L 2XXXX, XXKXX

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi



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Classe IIa (Class IIa)

<i>Nome prodotto</i> <i>(Product name)</i>	<i>Codice</i> <i>(Code)</i>
<i>Medicazioni di primo soccorso sterili</i> <i>(famiglia T01)</i>	<i>007XX¹</i>
<i>Pezze e Lunghette laparatomiche in garza o tnt sterili</i> <i>e non sterili</i> <i>(famiglia M12-13-14)</i>	<i>2XXXX – 4XXXX – 5XXXX –</i> <i>6XXXX – 8XXXX¹</i>
<i>Tamponi rotondi e piatti in garza o tnt sterili e non</i> <i>sterili (famiglia M18-19-20)</i>	<i>2XXXX – 4XXXX – 5XXXX –</i> <i>6XXXX – 8XXXX¹</i> <i>50947-700027</i>
<i>Zaffi in garza sterili e non sterili (famiglia M22)</i>	<i>3XXXX¹</i> <i>ZF4J00AXXXXX</i>

Il Direttore dell'Organismo Notificato
The Director of Notified Body
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Roberta Marcoaldi



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of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe IIa (Class IIa)

<i>Nome prodotto</i> (Product name)	<i>Codice</i> (Code)
<i>Set composti per intervento operatorio con Compresse plegate, Laparatomiche e Tamponi, in garza e tnt, sterili e non sterili (famiglia M30)</i>	<i>007XX¹</i>
<i>Strumentario chirurgico monouso, sterile e non sterile</i>	<i>MIXXX-YY-X²</i> <i>TXX</i>
<i>Custom pack invasivo, sterile o non sterile</i>	<i>CPXXXXX³</i> <i>11XXX.XX-X, 20XXX.XX-X</i> <i>66XXXXXX, 1915162,</i> <i>29XXX, 9604805</i> <i>9604834, 9514580</i>
<i>Pacco procedurale invasivo, sterile o non sterile</i>	
<i>Set chirurgico invasivo, sterile o non sterile</i>	
<i>Kit chirurgico invasivo, sterile o non sterile</i>	

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di cui il presente allegato tecnico è parte integrante, è da considerarsi riferito solo al/ai seguente/i prodotto/i soggetto/i a sorveglianza:

of which this technical sheet is an integral part, refers only to the following product(s) that are subject to surveillance:

Classe IIa (Class IIa)

<i>Nome prodotto (Product name)</i>	<i>Codice (Code)</i>
<i>Kit Medicazione post operatoria sterile (Piccolo – Medio – Grande) Aftercare Dressing Set (small – medium – large)</i>	<i>31711; 31712; 31713</i>
<i>Velpeau set post-operatoire, sterile (Grande plaie – Moyenneplaie – Petite plaie)</i>	<i>31766, 31765, 31764, 1100582, 1100584, 1100585</i>

I codici di cui sopra hanno il seguente significato, come da criteri di codifica presentati dalla Ditta e conservati presso questo Organismo Notificato:

¹X indicano le variazioni di misura, tipo di garza e numero degli strati

²MI: Metal Instrument; XXX: codice progressivo; YY: indica le varie lunghezze degli strumenti appartenenti alla stessa famiglia; X indica lo stato "sterile" del dispositivo.

³CP: indica la famiglia del dispositivo medico; XXXXX: codice progressivo.

⁴Y: lettera progressiva.

Valutazione della Conformità: vedi MOD-341-01-01 n. 351/20
Conformity assessment: see MOD-341-01-01 n. 351/20

Il Direttore dell'Organismo Notificato
The Director of Notified Body
(Dott.ssa Roberta Marcoaldi)

Roberta Marcoaldi

Ragione sociale
STS Medical Group AD
Industrial area Sokolovets
2800 Sandanski Blagoevgrad Bulgaria

29-Jul-24

Notified Body Confirmation Letter
Reference: contract n. 000133089

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, ICIM SPA, Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

STS Medical Group AD
Industrial area Sokolovets
2800 Sandanski Blagoevgrad Bulgaria
SRN manufacturer: BG-MF-000041809
SRN procedure pack producer: BG-PR-000041814

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the ICIM has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

ICIM SPA
Piazza Don Enrico Mapelli, 75
20099 Sesto San Giovanni MI
Identification on NANDO CE0425

Table 1: Devices covered by this letter and for which ICIM SPA is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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Table 2: Devices covered by this letter and for which ICIM SPA is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SECUSORB: compresses, balls, pads, laparotomy sponges, adhesive dressings	Class I devices placed on the market in sterile condition	N/A	Certificate QPS-0537-20 NB Istituto Superiore di Sanità
SECUTOOL: single-use surgical instruments	Class I devices placed on the market in sterile condition	N/A	Certificate QPS-0537-20 NB Istituto Superiore di Sanità
SECUTRAY: sterile procedure packs	Class I devices placed on the market in sterile condition	N/A	Certificate QPS-0537-20 NB Istituto Superiore di Sanità
SECUSORB: compresses, balls, pads, laparotomy sponges, adhesive dressings	Class IIa	N/A	Certificate QPZ-1941-20 NB Istituto Superiore di Sanità
SECUTOOL: single-use surgical instruments	Class IIa	N/A	Certificate QPZ-1941-20 NB Istituto Superiore di Sanità
SECUTRAY: sterile procedure packs	Class IIa	N/A	Certificate QPZ-1941-20 NB Istituto Superiore di Sanità

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/07/19	00	Initial issue

Remaining at your disposal for any clarification on the content of this letter, we take this opportunity to extend our best regards.

Mr. Edoardo Dossena
Sales Responsable Manager

Miss. Flavia Lepore
Sales Director

Strategic Industry

ICIM S.p.A.

Edoardo D'Amico

ICIM S.p. A.