



Notified Body 1023  
**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,**  
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

## EC Certificate - Production Quality Assurance No. 20 0183 QS/NB

The quality system of manufacturer

### **Medvida, Lda**

**Estrada de Viana/Catete – ZEE Luanda/Bengo, 1º Quadrante, km  
28, N° s/n, Município: Viana, Província: Luanda, Angola**

has been certified as meeting the requirements of

### **Directive 93/42/EEC on medical devices, Annex V**

for the following product category(ies):

### **Sterile Gauze Dressings Sterile Nonwoven Dressings**

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. The Notified Body has audited this system with limitation to those aspects of manufacture concerned with securing and maintaining sterile conditions. This part of quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance.

**Valid from:** 2020-05-12

**Valid until:** 2024-05-27

**First Issued:** 2020-05-12

**Revision:** -

Date: 2020-05-12



**Mgr. Jiří Heš**  
Representative of the Notified Body No. 1023



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**INSTITUTE FOR TESTING AND CERTIFICATION, Inc.**,  
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## Annex to EC Certificate No. 20 0183 QS/NB issued for manufacturer:

**Medvida, Lda**  
**Estrada de Viana/Catete – ZEE Luanda/Bengo, 1º Quadrante, km**  
**28, N° s/n, Município: Viana, Província: Luanda, Angola**

### Product(s):

**Name:** **Sterile Gauze Dressings**

**Trade name(s):** Medvida Sterile Swabs  
Sanus Sterile Swabs

### Model(s):

Dimensions - folded	Total dimensions	Number of plies
5 cm x 5 cm	15 cm x 20cm (tolerance -5%)	8
7.5 cm x 7.0 cm	25 cm x16 cm (tolerance -5%)	8
7.5 cm x 7.5 cm	15cm x 30 cm (tolerance -5%)	8
7.5 cm x 7.5 cm	30 cm x 30 cm (tolerance -5%)	16
10 cm x 10 cm	20 cm x 40 cm (tolerance -5%)	8
20 cm x 15 cm	60 cm x 40 cm (tolerance -5%)	8
40 cm x 20 cm	80 cm x 80 cm (tolerance -5%)	8
45 cm x 45 cm	50 cm x 180 cm (tolerance -5%)	4

**Class:** Is  
**GMDN:** 48134



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**Annex to EC Certificate No. 20 0183 QS/NB**  
issued for manufacturer:

**Medvida, Lda**  
**Estrada de Viana/Catete – ZEE Luanda/Bengo, 1º Quadrante, km**  
**28, N° s/n, Município: Viana, Província: Luanda, Angola**

**Name:** **Sterile Non-Woven Dressings**

**Trade name(s):** Medvida Sterile Swabs  
Sanus Sterile Swabs

**Model(s):**

Dimensions - folded	Total dimensions	Number of plies
5 cm x 5 cm	10 cm x 10 cm (tolerance -5%)	4
7.5 cm x 7.5 cm	15cm x 15 cm (tolerance -5%)	4
10 cm x 10 cm	20 cm x 20cm(tolerance -5%)	4
20 cm x 15 cm	40 cm x 30 cm (tolerance -5%)	4

**Class:** Is  
**GMDN:** 48131

**Facility(ies):**

Medvida, Lda

Estrada de Viana/Catete – ZEE Luanda/Bengo, 1º Quadrante, km 28, N° s/n,  
Município: Viana, Província: Luanda, Angola



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**28, N° s/n, Município: Viana, Província: Luanda, Angola**

### Certificate History:

Revision	Date	Reference Number	Action
	2020-05-12	803602843	Certification

Date: 2020-05-12  
Revision: -



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