



Sulejówek, 12.04.2021

DECLARATION OF CONFORMITY

SUMI spółka z ograniczoną odpowiedzialnością sp. k.
Drobiarska 35, 05-070 Sulejówek, Poland

hereby declare that below listed devices
comply with the appropriate requirements of the Medical Device Directive 93/42/EEC,
amended by Council Directive 2007/47/EC as applied to Class I, IIa and IIb
according to Annex IX

The quality control system has been verified by:

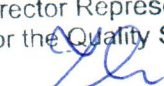
NEOEMKI LLC - Notified Body No. 1011
Directorate of Device Testing and Clinical Engineering

Albert Florian ut 3/A, H-1097 Budapest, Hungary

The implemented and maintained Quality Control System is certified according to:

EN ISO 13485:2016 No. 4-541-135-2012 valid till 20.12.2023
and EC Certificate No. 5-881-200-2004 valid till 26.05.2024
(Full Quality Assurance System, Directive 93/42/EEC on Medical Devices,
Annex II excluding section 4).

Director Representative
for the Quality System


Zbigniew Milewski

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05-070 SULEJÓWEK, UL. DROBIARSKA 35
TEL./FAX (22) 783-30-23, 783-30-25
NIP 113-00-29-764

List of products

Class I sterile :

1. Guedel airways
2. Nasal oxygen set
3. Nasopharyngeal airways
4. Suction connecting tubes
5. Connectors, adaptors
6. Tubings, bubble tubings
7. Silicone tubings

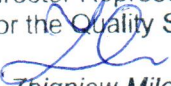
Class IIa:

1. Tracheal tubes
2. Tracheal tubes accessories
3. Tracheal intubation stylets, introducers, guides
4. Bronchial tubes, single and double lumen
5. Bronchial tubes accessories and connectors
6. Tracheostomy double lumen bronchial tubes
7. Laryngeal masks
8. Hi Capno
9. Suction catheters
10. Stomach tubes
11. Duodenal tubes
12. Suction handles
13. Suction handles, set
14. Suction handles, with filter
15. Closed suction systems
16. Silicone corrugated breathing tubings
17. Cricothyrotomy set
18. Percutaneous tracheostomy set

Class IIb:

1. Tracheostomy tubes
2. KAN Tracheostomy tubes
3. SUMINI tracheostomy tubes
4. Tracheostomy tubes accessories
5. Feeding tubes
6. Urology catheters - Nelaton, Tiemann

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