



Sulejówek, 08.03.2019

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:

EMKI - Notified Body No. 1011
Directorate of Device Testing and Clinical Engineering
as part National Institute of Pharmacy and Nutrition

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. 4-480-135-1712 valid till 20.12.2020
and EC Certificate No. 5-831-200-1801 valid till 15.01.2023
(Full Quality Assurance System, Directive 93/42/EEC on Medical Devices,
Annex II excluding section 4).

Director Representative
for the Quality System


Zbigniew Milewski

SUMI spółka z ograniczoną odpowiedzialnością sp.k.
05-070 SULEJÓWEK, UL. DROBIARSKA 35
TEL./FAX (22) 783-30-23, 783-30-25
NIP 113-00-29-764



Attachment to Declaration of Conformity

List of products

Class I:

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. Suction catheters
9. Stomach tubes
10. Duodenal tubes
11. Suction handles, set
12. Closed suction systems
13. Silicone corrugated breathing tubings

Class IIb:

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

Director Representative
for the Quality System


Zbigniew Milewski

SUMI spółka z ograniczoną odpowiedzialnością sp.k.
05-070 SULEJÓWEK, UL. DROBIARSKA 35
TEL./FAX (22) 783-30-23, 783-30-25
NIP 113-00-29-764