DECLARATION OF CONFORMITY

MEDICAL DEVICES PER EUROPEAN DIRECTIVE 93/42/EEC

Legal Manufacturer:

Extrudan Sp. z o.o.
Dąbrówka, ul. Polna 5
62 – 070 Dopiewo

We hereby declare that the CE marked sterile and non-sterile products, specified below, conform to the products covered by the applicable "CE Marking of Conformity Certificate"(reference number and issuance date provided below), delivered by DNV GL Presafe AS, Notified **Body Identification Number 2460**, in accordance with Annex V of Council Directive 93/42/EEC concerning medical devices.

In addition, we ensure and declare that the CE marked sterile and non-sterile products, as mentioned and falling within **Class IIa** as per Annex IX, **Rule 7** applies to Suction Equipment, Insufflation Tubes and **Rule 5** applies to Oxygen Catheters, Suction Catheters, meet the provisions of the current Directive 93/42/EEC which apply to them.

List of products covered by this Declaration of Conformity:

Product Description	**Product Name**
SUCTION EQUIPMENT	• SUCTION SETS • SUCTION PIECES • CONNECTING TUBES
INSUFFLATION TUBES	• INSUFFLATION TUBE WITH FILTER • INSUFFLATION TUBE WITHOUT FILTER
OXYGEN CATHETERS	• OXYGEN CATHETERS WITH COMPRESS • OXYGEN CATHETERS WITH ADJUSTABLE COMPRESS
SUCTION CATHETERS	• SUCTION CATHETERS STRAIGHT • SUCTION CATHETERS COUDE

The declaration is based on the application of the **Quality Systems** of Extrudan Sp. z o.o., which meets the requirements of:

- CE Certificate - No. 11452 – 2017 – CE – POL – NA – PS
- EN ISO 13485:2016 - No. 10000370276-PA-NA-SVK
- EN ISO 9001:2015 - No. 267821-2018-AQ-POL-FINAS
- EN ISO 14001:2015- No. 204513-2016-AE-POL-RvA

The above certificates have been issued by DNV GL Presafe AS to Extrudan Sp. z o.o in respect of productions at the indicated site and for products mentioned in the scope of the certification.

This Declaration of Conformity is issued under the exclusive responsibility of the manufacturer.

The Declaration of Conformity is valid for all products described here above until the expiration date indicated on the CE Marking of Conformity Certificate

For supporting information, see the following attachments:

1. Statements
2. List of Extrudan products TF 00.1

EXTRUDAN Single Use Products Since 1984
Elektronicznie podpisany przez Olga Ratza-Krasucka
Data: 2021.06.01 11:36:43 +02'00'

Date: 2021-06-01

Signed by: Olga Krasucka - Quality Manager

ATTACHMENT 1

Extrudan Sp. z o.o. hereby declares the following for the products:

Product Description	Product Name
SUCTION EQUIPMENT	• SUCTION SETS • SUCTION PIECES • CONNECTING TUBES
INSUFFLATION TUBES	• INSUFFLATION TUBE WITH FILTER • INSUFFLATION TUBE WITHOUT FILTER
OXYGEN CATHETERS	• OXYGEN CATHETERS WITH COMPRESS • OXYGEN CATHETERS WITH ADJUSTABLE COMPRESS
SUCTION CATHETERS	• SUCTION CATHETERS STRAIGHT • SUCTION CATHETERS COUDE

- Products are for single use, i.e., single-patient, single procedure and single purpose use. Products should not be reprocessed and re-used.
- Products are **LATEX-FREE**
- Products do **not** contain **Phthalates**.
  Extrudan's products have been DEHP-free since 25.02.2015 (products DO NOT CONTAIN toxic substances). Softener used as the replacement is DEHT [bis(2-ethylhexyl) benzene-1,4 dicarboxylate].
  This statement comprises the medical device, it's packaging as well as its manufacturing processes.
- Based on our present knowledge, the product mentioned here above **do not contain substances** of the **REACH** Candidate List.
  Extrudan is committed to making an effort to ensure that all Extrudan's products are manufactured in compliance with the EU's REACH legislation and will, therefore, continue to work closely with our suppliers in order to get available and relevant information from our suppliers.
  According to Article 33 of the REACH Regulation, as soon as we gain knowledge of any substances of very high concern (SVHC) as specified in the latest update of ECHAS candidate list in concentrations over 0.1% in our products, we will send corresponding information.
- Products do **not** contain **tissue of biological origin**, i.e., do not contain tissue of animal origin or (human) blood derivatives.
- Products do **not** contain **traces of heavy metals.**

EXTRUDAN® Single Use Products Since 1984
Elektronicznie podpisany przez Olga Ratza-Krasucka
Data: 2021.06.01 11:37:12 +02'00'

Date: 2021-06-01

Signed by: Olga Krasucka - Quality Manager