



Manufacturer's Declaration

in relation to 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, in particular with respect to the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates)

Manufacturer name	ZARYS International Group sp. z o.o. sp.k.
Manufacturer address and contact details	ul. Pod Borem 18, 41-808 Zabrze, Poland
Single Registration Number (SRN)	PL-MF-000000410

Notified body name and address	TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Germany
Notified body number	0197
Directive Certificate number(s) to which this confirmation is made	See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	See attached schedule
End date of extended validity/transition period	See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- ✓ Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.
- ✓ Expired/expires *after* 20 March 2023:
 - ✓ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.



➤ **Quality Management System (QMS)**

- ✓ A QMS in accordance with Article 10(9) MDR is in place.

➤ **Device(s) as listed in the attached schedule**

- ✓ The device(s) continue to comply with the AIMDD or MDD.
- ✓ There are no significant changes in the design and intended purpose.
- ✓ The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

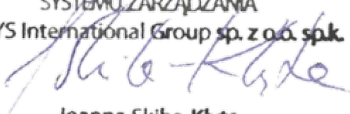
Signed for and on behalf of the manufacturer:

Full Company Name: ZARYS International Group spółka z ograniczoną odpowiedzialnością spółka komandytowa

Location & Date: Zabrze, 1.03.2024

Name, Title: Joanna Skiba-Klyta, Quality and Regulatory Affairs Department Coordinator/ Management Board's Representative for Integrated Management Systems

Contact Details: qm@zarys.pl

PEŁNOMOCNIK ZARZĄDU DS. ZINTEGROWANEGO
SYSTEMU ZARZĄDZANIA
ZARYS International Group sp. z o.o. sp.k.

Joanna Skiba-Klyta

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	Device Classification	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	End date of extended validity / transition period
Sterile and non-sterile cutting gauze	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Non-sterile dressing gauze	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile gauze swabs (with or without X-ray thread)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile gauze lap sponges (with X-ray thread/ with X-ray chip)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile gauze balls (with or without X-ray thread)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile gauze rolls (with or without X-ray thread)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile and non-sterile non-woven swabs (with or without X-ray thread)	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile paraffin gauze dressings	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile three-way stopcocks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile transfusion sets for single use	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile infusion sets for single use	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile extension tubes for infusion pump	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile endotracheal tubes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile tracheostomy tubes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile breathing circuits	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile catheter mounts	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Non-sterile anaesthetic masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile laryngeal masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile oxygen masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile Venturi masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile non-rebreath masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile nebulizer masks	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile nasal oxygen cannulas	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile nebulizers	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile oxygen tubing	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile suction catheters	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile feeding tubes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile stomach and duodenal tubes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile urology catheters	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile surgical suction sets	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile surgical suction cannulas	Class IIa	DD 1023663-1	26 May 2024	31 December 2028



Sterile syringes for single use	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile insulin syringes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile tuberculin syringes	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile hypodermic needles	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile insulin pen needles	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile blood lancets	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile IV cannulas	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile needle free valves	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile surgical gloves	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Sterile procedure kits	Class IIa	DD 1023663-1	26 May 2024	31 December 2028
Elastic bandages	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Adhesive cannula fixation dressings	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Adhesive wound dressings	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Eye pads	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Incise films	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Transparent film dressings	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Absorbent wound dressings	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Surgical gowns	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Surgical drapes	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Sets of surgical drapes	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Fluid collection pouches	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Nelaton catheters	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Vaginal speculums	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Cervical brushes	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Urine bags	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Enema bags	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Tongue depressors	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Oropharyngeal airways	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Intubation stylets	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Endotracheal tube holders	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Suction tubes	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Withdrawal cannulas	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Cannula stoppers	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Umbilical cord clamps	Class I sterile	DD 1023663-1	26 May 2024	31 December 2028
Sterile surgical sets	Class IIa	HD 1023663-1	26 May 2024	31 December 2028
Sterile procedure kits	Class IIa	HD 1023663-1	26 May 2024	31 December 2028
Sterile surgical sets	Class IIb	HD 1023663-1	26 May 2024	31 December 2028
Surgical gowns	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028
Surgical drapes	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028
Sets of surgical drapes	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028
Procedure kits	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028
Knitted bandages	Class I sterile	HD 1023663-1	26 May 2024	31 December 2028