

Declaration of Conformity Cover Page Deckblatt Konformitätserklärung

Key Surgical Distributes CE marked Personal Protective Equipment Below is a list of Personal Protective Equipment in the EU that Key Surgical Distributes with the Corresponding Vendor (Manufacturer) Item Number. This document is only utilized to link the Supplier item number in the attached Declaration of Conformity with the corresponding Key Surgical Item Number.

Key Surgical vertreibt CE gekennzeichnete persönliche Schutzausrüstung. Nachfolgend ist eine Liste von persönlicher Schutzausrüstung in der EU, die Key Surgical mit der entsprechenden Artikelnummer des Lieferanten (Herstellers) vertreibt. Dieses Dokument dient nur dazu, die Artikelnummer des Lieferanten in der beigefügten Konformitätserklärung mit der dazugehörigen Key Surgical Artikelnummer gegenüberzustellen.

Product Name	Key Surgical Item Number	Vendor Item Number	GTIN – Include all packaging levels
Produktname	Key Surgical Artikelnummer	Lieferanten Artikelnummer	GTIN – Einbeziehung aller Verpackungsebenen
Doppel-OP-Klemmbezüge	5-10-110-Z	5-10-110-Z	04260491420008
OP-Hakenbezüge	5-10-120	5-10-120	04260491420015
OP-Hakenbezüge	5-10-180	5-10-180	04260491420022
Doppel-OP-Klemmbezüge	5-10-180-Z	5-10-180-Z	04260491420220
OP-Hakenbezüge	5-10-200	5-10-200	04260491420039
OP-Hakenbezüge	5-10-250	5-10-250	04260491420046
OP-Hakenbezüge	5-10-300	5-10-300	04260491420053
OP-Hakenbezüge	5-25-120	5-25-120	04260491423580
OP-Hakenbezüge	5-25-150	5-25-150	04260491420060
OP-Hakenbezüge	5-25-200	5-25-200	04260491420077
OP-Hakenbezüge	5-25-250	5-25-250	04260491420084
OP-Hakenbezüge	5-25-300	5-25-300	04260491420091
OP-Hakenbezüge	5-25-400	5-25-400	04260491420107
OP-Hakenbezüge	5-25-500	5-25-500	04260491420114
OP-Hakenbezüge	5-30-220	5-30-220	04260491420121
OP-Hakenbezüge	5-30-310	5-30-310	04260491420237
OP-Hakenbezüge	5-35-280	5-35-280	04260491420138
OP-Hakenbezüge	5-35-350	5-35-350	04260491420145
OP-Hakenbezüge	5-40-220	5-40-220	04260491420152
OP-Hakenbezüge	5-45-240	5-45-240	04260491420169
OP-Hakenbezüge	5-50-310	5-50-310	04260491420176
OP-Hakenbezüge	5-50-330	5-50-330	04260491420183
OP-Hakenbezüge	5-80-230	5-80-230	04260491420190
OP-Hakenbezüge	5-80-300	5-80-300	04260491420206
OP-Hakenbezüge	5-80-350	5-80-350	04260491423658
OP-Hakenbezüge	5-80-400	5-80-400	04260491420213



**WYTWÓRNA SPRZĘTU MEDYCZNEGO
MEDICAL EQUIPMENT PRODUCER**

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EC DECLARATION OF CONFORMITY
no DC/A18e/2021

The undersigned Katarzyna Meger, owner of Medical Equipment Producer „GALMED”, Address: Łęczycka 65, 85-737 Bydgoszcz, tel. (+48 52) 3420399, fax (+48 52) 3426688, herewith declares that the products:

COVERS FOR SURGICAL INSTRUMENTS Jo-Lo
Covers for hooks
Covers for forceps

Medical products class IIa (Annex IX, rule 6)

- are in conformity with the Essential Requirements and provisions of the Council Directive 93/42/EEC – Medical Devices (amendment M5:2007, C1:2007),
- are in conformity with Polish regulations - Act on medical products dated 20.05.2010 (Dz.U. 2010, No 107, pos. 679 with amendment Dz.U. 2015, poz. 1918)
- are in conformity with EN-ISO 13485:2016 standard, and relevant standards harmonized with 93/42/EEC Directive.
- are sterilized in process which complies the requirements of EN ISO 11135:2014.
- are subject to the procedure set out in Annex II of the Directive 93/42/EEC - W.S.M. GALMED have established full Quality Management System certified to EN ISO 13485:2012 and under surveillance by Notified Body ID-Nr 2274, TÜV NORD Polska Sp. z o.o., Katowice, Poland.

CE 2274

This Declaration of Conformity loses its validity
in the day of expiration of Certificate, which is 24.05.2024.

Bydgoszcz, date 2021-05-25


Signature