

CE DECLARATION OF CONFORMITY

ANNEX 1

Etropal JSC., 191, Russki str., Etropole, Bulgaria,

Declare under their responsibility that the products,

MEDICAL KITS FOR SINGLE USE

**(Class II a, rule 4 and rule 6, according Council Directive 93/42/EEC
and Directive 2007/47/EO)**

are manufactured and controlled in conformity with the procedures of Quality Management System according to ISO 13485:2016, meet essential requirements of Annex I of the MDD 93/42/EEC and have been approved by KIWA Cermet -Italy.

- **EN ISO 11135:2014** Sterilization of product health care. ethylene oxide. Requirements for development, validation and routine control of sterilization process for medical devices.
- **ISO 10993-1:2009** Biological evaluation of medical devices, Part 1: Evaluation and testing
- **ISO 10993-7:2008** Biological evaluation of medical devices, Part 7: Ethylene oxide sterilization residuals
- **EN ISO 14971:2012** Medical devices - Application of risk management to medical devices
- **European Pharmacopoeia**

This product is carrying the CE - Mark in accordance with the European Directive 93/42/EEC and Directive 2007/47/EO, concerning medical devices and has been approved by Notified Body Number 0476 **KIWA Cermet** -Italy /

EC Quality Assurance System Certificate

Reg. number MED 31033

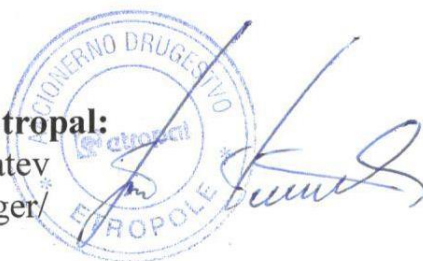
Issuing date 16.09.2011

Expiring date 26.05.2024

On behalf of Etropal:

Eng. Plamen Patev

/General Manager/



Date : 11.05.2021

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LIST of category and reference of medical kits

CATEGORY	REFERENCE
DRESSING KITS	CK-101, CK-102, CK-103, CK-104, CK-105, CK-106, CK-107, CK-108, CK109; CK-110, CK-111, CK-112, CK-113, CK-114, CK-115, CK-116, CK-117, CK-118, CK-119, CK-120, CK-121, CK-122, CK-123; CK-124, CK-125, CK-126, CK-127, CK-128129-CK, CK-210
SUTURE PROCEDURE KITS	CK-204, CK-205, CK-206, CK-207, CK-208, CK209
BIOPSY KITS	CK-201, CK-202, CK-203
CUSTOM MADE KITS	CK - 3XX; CK 4XX; CK - 5XX; CK 6XX