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: Evaluationand 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 15.09.2021

On behalf of Etropal:
Eng. Plamen Patev
/General Manager/

Date : 03.01.2020

ANNEX 1

L I S T

of category and reference of medical kits

CATEGORY		REFERENCE
DRESSING KITS	WITH DRAPE	CK-101, CK-102, CK-103, CK-104, CK-105, CK-106, CK-107, CK-108, CK-110, CK-111, CK-112, CK-113, CK-114, CK-115, CK-116, CK-117, CK-118, CK-119, 129-CK, CK-210
	WITHOUT DRAPE	CK109, CK-120, CK-121, CK-122, CK-123, CK-124, CK-125, CK-126, CK-127, CK-128.
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 4XX
CUSTOM MADE KITS Disrtributed by Novomed Group		CK - 3XX (LCH Medical products) CK - 5XX (Gyineas and Laboderm)