



AB 2017/745 UYGUNLUK BEYANI
EU DECLARATION OF CONFORMITY

İMALATÇI / MANUFACTURER : **HONNES SAĞLIK VE ENDÜSTRİYEL ÜRÜNLERİ A.Ş.**

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SINIFLANDIRMA : **AB 2017/745 Kural I, Sınıf-1 diğer (steril ve ölçme fonksiyonu olmayan)**
CLASSIFICATION **EU 2017/745 Medical Device Regulation-CLASS I**

UYGUNLUK DEĞERLENDİRME : **EU 2017/745 Tıbbi Cihaz Direktifi-**
CONFIRMITY ASSESMENT **EK II & III-AT Uygunluk Beyanı**
EU 2017/745 Medical Device Regulation
Annex II & III per article 52.7

ÜRÜN ADI / PRODUCT NAME : *Clivex*

ÜRÜN TANIMI / PRODUCT DESCRIPTION :

ÜRÜN ADI/PRODUCT NAME	GMDN KODU/GMDN CODE	GMDN ADI/GMDN NAME
C101 Clivex Cotton Surgical Tape 5m x 1,25cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C102 Clivex Cotton Surgical Tape 5m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C105 Clivex Cotton Surgical Tape 5m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C107 Clivex Cotton Surgical Tape 5m x 7,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C110 Clivex Cotton Surgical Tape 5m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>

C1201 Clivex Cotton Surgical Tape 5m x 1,25cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C1202 Clivex Cotton Surgical Tape 5m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C1205 Clivex Cotton Surgical Tape 5m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C1207 Clivex Cotton Surgical Tape 5m x 7,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C1210 Clivex Cotton Surgical Tape 5m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C1101 Clivex Cotton Surgical Tape 9,14m x 1,25cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C1102 Clivex Cotton Surgical Tape 9,14m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C1105 Clivex Cotton Surgical Tape 9,14m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C1107 Clivex Cotton Surgical Tape 9,14m x 7,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C1110 Clivex Cotton Surgical Tape 9,14m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C201 Clivex Silk Surgical Tape 5m x 1,25cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C202 Clivex Silk Surgical Tape 5m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C205 Clivex Silk Surgical Tape 5m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C207 Clivex Silk Surgical Tape 5m x 7,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C210 Clivex Silk Surgical Tape 5m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C2501 Clivex Silk Surgical Tape 5m x 1,25cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C2502 Clivex Silk Surgical Tape 5m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C2505 Clivex Silk Surgical Tape 5m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>

C2507 Clivex Silk Surgical Tape 5m x 7,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C2510 Clivex Silk Surgical Tape 5m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C2101 Clivex Silk Surgical Tape 5m x 1,25cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C2102 Clivex Silk Surgical Tape 9,14m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C2105 Clivex Silk Surgical Tape 9,14m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C2107 Clivex Silk Surgical Tape 9,14m x 7,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C2110 Clivex Silk Surgical Tape 9,14m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
IC-H4502 Clivex Elastic Fixation Tape 5m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
IC-H4505 Clivex Elastic Fixation Tape 5m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
IC-H4510 Clivex Elastic Fixation Tape 5m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
IC-H4102 Clivex Elastic Fixation Tape 10m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
IC-H4105 Clivex Elastic Fixation Tape 10m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
IC-H4110 Clivex Elastic Fixation Tape 10m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
IC-H4115 Clivex Elastic Fixation Tape 10m x 15cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
IC-H4120 Clivex Elastic Fixation Tape 10m x 20cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
IC-H4130 Clivex Elastic Fixation Tape 10m x 30cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C905 Clivex Roll Transparent Film (PU) 9,14m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C910 Clivex Roll Transparent Film (PU) 9,14m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>

C915 Clivex Roll Transparent Film (PU) 9,14m x 15cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C502 Clivex Microporous Surgical Tape 5m x 2,5cm	34864	<i>B Bandaj, yapışkan Bandage, Adhesive</i>
C505 Clivex Microporous Surgical Tape 5m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C5101 Clivex Microporous Surgical Tape 9,14m x 1,25cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C5102 Clivex Microporous Surgical Tape 9,14m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C5105 Clivex Microporous Surgical Tape 9,14m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C5107 Clivex Microporous Surgical Tape 9,14m x 7,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C5110 Clivex Microporous Surgical Tape 9,14m x 10cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C301 Clivex Perforated Transparent Surgical Tape 5m x 1,25cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C302 Clivex Perforated Transparent Surgical Tape 5m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C305 Clivex Perforated Transparent Surgical Tape 5m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C312 Clivex Perforated Transparent Surgical Tape 9,14m x 1,25cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C325 Clivex Perforated Transparent Surgical Tape 9,14m x 2,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C350 Clivex Perforated Transparent Surgical Tape 9,14m x 5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C375 Clivex Perforated Transparent Surgical Tape 9,14m x 7,5cm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C8025 Clivex Injection Plaster 25mm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
C8125 Clivex Injection Plaster 25mm	34864	<i>Bandaj, yapışkan Bandage, Adhesive</i>
CS615 Clivex Elastic Bandage 6cm x 4,5m	15047	<i>Bandaj, elastic / Bandage, elastic</i>

CS815 Clivex Elastic Bandage 8cm x 4,5m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CS1015 Clivex Elastic Bandage 10cm x 4,5m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CS1215 Clivex Elastic Bandage 12cm x 4,5m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CS1515 Clivex Elastic Bandage 15cm x 4,5m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CS2015 Clivex Elastic Bandage 20cm x 4,5m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CH054 Clivex Gauze Bandage 5cm x 4m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CH064 Clivex Gauze Bandage 6cm x 4m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CH074 Clivex Gauze Bandage 7cm x 4m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CH084 Clivex Gauze Bandage 8cm x 4m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CH104 Clivex Gauze Bandage 10cm x 4m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CH124 Clivex Gauze Bandage 12cm x 4m	15047	<i>Bandaj, elastic / Bandage,elastic</i>
CH154 Clivex Gauze Bandage 15cm x 4m	15047	<i>Bandaj, elastic / Bandage,elastic</i>

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YUKARIDA TANIMLI ÜRÜNÜN, TALİMATLAR KURULU TIBBİ CİHAZLAR KARARNAMESİ EU 2017/745 İÇİN GEREKLİ ŞARTLARA UYGUN OLDUĞUNU BEYAN EDERİZ. DESTEKLEYİCİ TÜM BELGELER ÜRETİCİNİN TESİSLERİNDE BULUNMAKTADIR.

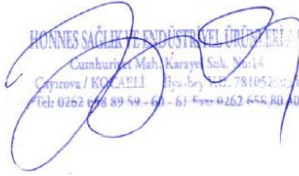
WE HEREWITH DECLARE THAT THE ATTACHED PRODUCT MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE EU 2017/745 FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

İLGİLİ STANDARTLAR / STANDARTS APPLIED :

EN ISO 13485:2016	AB 2017 / 745	EN ISO 14971:2012
EN ISO 15223-1:2021	EN 1041:2008	EN ISO 14155:2011
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	EN ISO 10993-10:2009
EN ISO 62366:2008	EN 980:2008	

ŞEHİR, DÜZENLEME TARİHİ : KOCAELİ / 11.02.2022
PLACE, DATE OF ISSUE

İMZA/ SIGNATURE : **SERDAR AĞALAR**
GENEL MÜDÜR YARDIMCISI
ASSISTANT GENERAL MANAGER



HONNES SAĞLIK VE ENDÜSTRİYEL ÜRÜNLERİ
Cumhuriyet Mah. Karayol. Sok. No:14
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C E R T I F I C A T E

Production Quality Assurance Medical Devices Directive 93/42/EEC Annex V

Company Name : Honnes Sağlık ve Endüstriyel Ürünleri A.Ş.

Company Address : Cumhuriyet Mah. Karayel Sokak No:14 Çayırova KOCAELI / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex V

Product : Sterile Ready To Use Wound Dressing (Nonwoven Polyurethane) - Class I
Sterile Eye Pad - Class Is
Sterile Haemostatic Pressure Band - Class Is
Steril Catherer Fixation Band - Class Is
- Nonwoven, Transparent
- Polyurethane Nonwoven With Pad
- Transparent With Pad
- Polyurethane With Pad

GMDN : 34864, 11661

Certificate Number : M.2018.106.9658

Report Number : MD.3508.YB

Initial Assessment Date : 19.01.2016

Registration Date : 10.05.2018

Recertification Assessment Date : 05.12.2018

Reissue Date / No : 27.02.2019/01

Revision Date /No : -

Expiry Date : 07.02.2024


UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.



Address: Mutfukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr



INTERNATIONAL CERTIFICATION

Certificate

HONNES SAGLIK VE ENDUSTRIYEL URUNLERI A.S.

company,

CUMHURİYET MAH.KARAYEL SK. NO:14
CAYIROVA / KOCAELI / TÜRKİYE

in address,

STERILE AND NON-STERILE SINGLE AND MULTI-USE NONWOVEN, POLYURETHANE, POLYETHYLENE, TRANSPARENT AND ANTIMICROBIAL FEATURES SURGICAL INVASIVE, NATURAL INVASIVE, PHYSICAL AND CHEMICAL BARRIER FUNCTIONAL DRESSING AND DRAWINGS, PRIMARY WOUND CLOSURE MATERIALS, OPEN WOUND, PRESSURE WOUNDS, BIRTH AND SURGICAL INTERFERENCE DRESSINGS AND CLOSURE SETTINGS, GASAMA VESTERILERY, FEMALES AND CLOSURE SETTINGS, FOSTERILERY, OCULERUS, SYNTHETIC PLASTER AND SPLINT PRODUCTS, FIRST AID WOUND TAPES, KINESIO TAPE, ELASTIC BANDAGE, SELF-ADHESIVE BANDAGE, HEATING FLASTER TAPE, NOSE TAPE, MASK, SURGICAL MASK, DISINFECTANTS, SOLUTIONS, SILICONE PAPER, HEAT SEAL PAPER, COLD SEAL PAPER, MEDICAL PAPER, EXAMINATION AND SURGICAL GLOVES, NON-STERILE GARMENT, GALOSHAF, EKG ELECTRICITY INSTRUMENT, STERILE SYRINGE AND STERILE SERUM SETS, ELASTIC WRAPPING CLOTH, STERILE SPANISH COMPRESS, STERILE STRIP FLASTER, COOLING GEL, BREATHING TAPE, HEEL TAPE, DESIGN, MANUFACTURING, SALE CONTRACTING PRODUCTION OF THESE MATERIALS

on scope,

ISO 13485:2016

Medical Devices-Quality Management System

Not Applicable: -
Is applicable.

Certificate No : C-US-2233500
Date of Certification : 10.12.2022
Date of Issue : 10.12.2022
Expiry Date : 09.12.2023

Certification Period : 3 Years
Revision No : 00
Revision Date : -



TGS
International Certification



The validity of the certificate depends on observance of the TGS rules. Certificate validity may be checked on www.tgscert.com

TGS INTERNATIONAL CERTIFICATION TECHNICAL CONTROL AND SURVEILLANCE SERVICES CO. LTD.

Serifali Mh. Tavukcuyolu Cd. No:256/4 Umraniye/İSTANBUL
Phone: +90 216 327 09 77(Pbx) Fax: +90 216 546 05 70

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