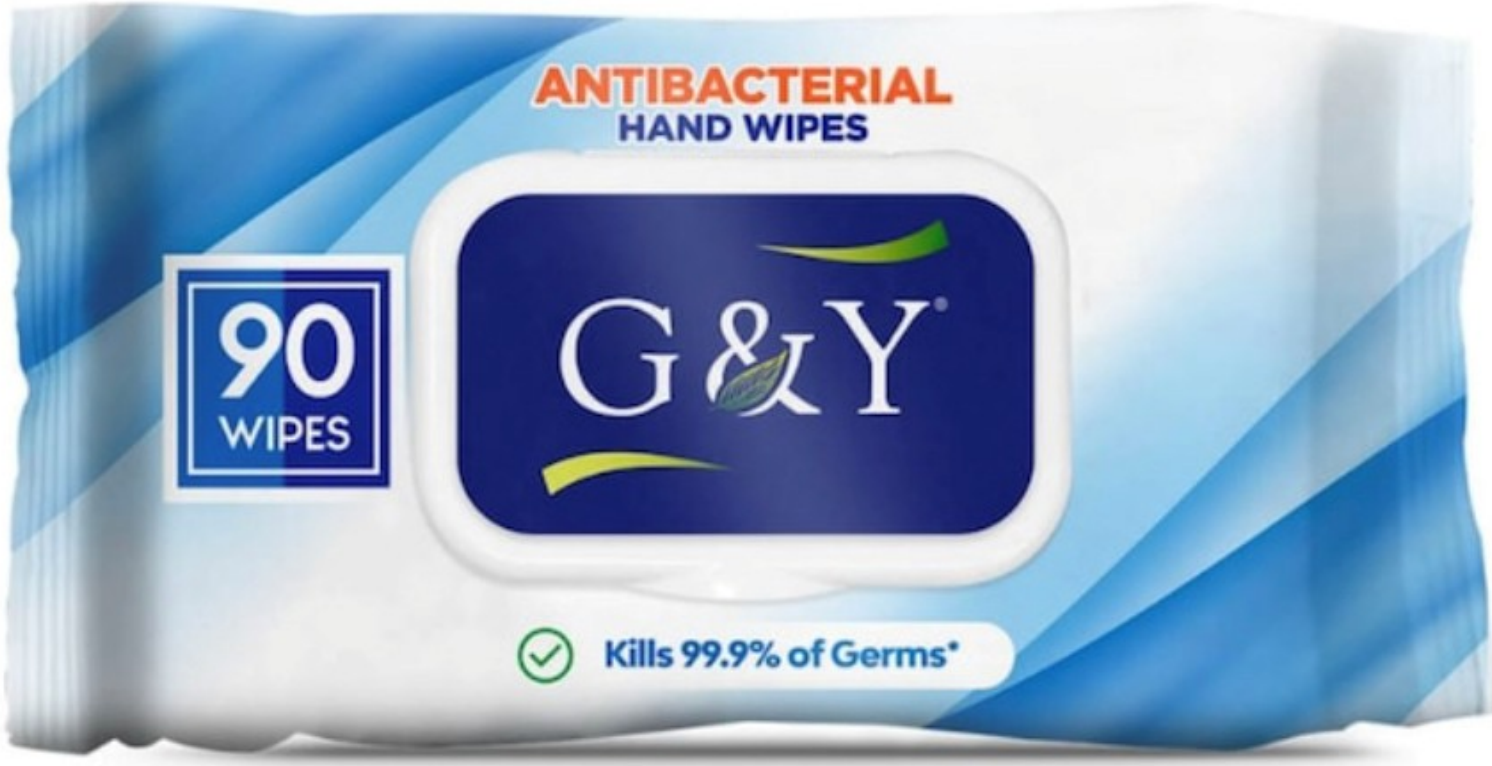
ANTIBACTERIAL
HAND WIPES
90
WIPES
G&Y
Kills 99.9% of Germs*

# Certificate of Registration
# 2020

*This is to certify that the below mentioned Drug of*

**ERUSLU SAGLIK URUNLERI SANAYI VE TICARET ANONIM SIRKETI**

ERUSLU SAGLIK URUNLERI, NO: 3 BASPINAR OSB MAHALLESI 4, BOLGE 83424 NOLU CADDE SEHITKAMIL, GAZIANTEP, TURKEY - 27060

*is successfully listed with U.S. Food and Drug Administration as required by 21 CFR Part 207, Subpart D.*

| | |
|---|---|
| **Proprietary Name** | **G AND Y ANTIBACTERIAL HAND WIPES** |
| **NDC Labeler Code** | **77613-010-20, 77613-010-90** |
| **SPL Submitted by** | **Liberty Management Group Ltd.** |
| **Certificate Number** | **6005300620** |

*This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.*

*The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Liberty Management Group Ltd. is not affiliated with the U.S. Food and Drug Administration*

LMG LIBERTY MANAGEMENT GROUP LTD.
75 Executive Drive, Aurora, Illinois, USA
www.fdahelp.us

Manoj Zacharias
President
Liberty Management Group LTD.
Dated: May 30, 2020

7.28.2020

# Letter of Appointment

Dear Sir or Madam,

G&Y Products, Inc., a New Jersey corporation with its principal offices at 25 Shady St., Paterson New Jersey 07524 USA, hereby confirm that we have appointed:

***Boes Aviation and Asset Management LLC***

As our non-exclusive Distributor being entitled to promote, negotiate, tender, sell and exhibit all of the products offered by G&Y Products, Inc., in the United States of America.

This appointment is valid until further notice.

If you have any questions, please do not hesitate to contact me at veli.ozdemir@gyproduct.com.

Best Regards,

Veli Ozdemir
G & Y Products Inc
President

# SAFETY DATA SHEET

**Issuing Date** 13-Jan-2020 **Revision Date** 01-Apr-2020 **Revision Number** 3

## 1. IDENTIFICATION

**Product identifier**

**Product Name** **G&Y ® Antibacterial Hand Wipes**

**FDA National Drug Code** 77613-010-20, 77613-010-90, 77613-011-20, 77613-011-90

**EPA Registration Number** Pending

**Recommended use of the chemical and restrictions on use**

**Recommended Use** General Purpose Cleaner

**Details of the supplier of the safety data sheet**

**Supplier** Eruslu Saglik Urunleri Sanayi ve Ticaret Anonim Sirketi

**Supplier Address** 4. Organized Industrial Zone 83424 Street
No: 3 Şehitkamil, Gaziantep, Turkey

**Telephone** 90-342-357-02-00

**Emergency telephone number**

**Emergency telephone number** 90-342-357-02-00

## 2. HAZARDS IDENTIFICATION

**Hazard Classification**

It is not classified as dangerous substances according to European Union Regulations. Important Risk Information for Human and Environment: According to the European Union Regulations, it does not fall into a class of substances that harm human health and the environment.

**Hazard Statements**

There are not hazardous situations.

**Pictograms**

There are not hazardous situations.

**Precautionary Statements**

Do not expose to direct sunlight. After the packaging is opened, consume within 3 months. Do not throw in the toilet

**Description of other hazards**

There are not hazardous situations.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS-No | Percent |
|---|---|---|
| AQUA | 7732-18-5 | 98.376 |
| C12-15 PARETH-12 | 68131-39-5 | 0.4 |
| PHENOXYETHANOL | 122-99-6 | 0.65 |
| DEHYDROACETIC ACID | 520-45-6 | 0.048 |
| BENZALKONIUM CHLORIDE | 68424-85-1 | 0.13 |
| BENZOIC ACID | 65-85-0 | 0.096 |
| GLYCERIN | 56-81-5 | 0.1 |
| TETRASODIUM GLUTAMATE DIACETATE | 51981-21-6 | 0.2 |

## 4. FIRST AID MEASURE

**First Aid Measures**

**General Advice** Show this safety data sheet to the doctor in attendance.

**Skin contact** No adverse effect is expected. However, in case of redness, burning or itching, wash with plenty of water. If irritation persists, consult your doctor and do not use the product.

**Eye contact** Rinse cautiously with water for several minutes. If eye irritation persists, consult a doctor.

**Inhalation** If symptoms develop move victim to fresh air. If breathing is difficult, (trained personnel should) give oxygen. If symptoms persist, call a physician.

**Ingestion** Drink 1 or 2 glasses of water. Get medical attention if symptoms occur.

## 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing agents**
The product is not flammable, use fire extinguishing methods suitable to surrounding conditions. $CO_2$, foam, dry chemical.

**Special protective equipment for firefighters**
No data available

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions** No special personal protective equipment is required. Keep away from food, drink and animal foods

**Environmental precautions** See Section 12 for additional Ecological Information.

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

## 7. HANDLING AND STORAGE

**Precautions for safe handling**

**Handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

**Conditions for safe storage, including any incompatibilities**

**Storage** Keep containers tightly closed in a dry, cool and well-ventilated place.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| | |
|---|---|
| **General protective and hygienic measures** | No special protective equipment required. |
| **Breathing equipment** | No special protective equipment required. |
| **Protection of hands** | No special protective equipment required. |
| **Eye protection** | No special protective equipment required. |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **Form** | Wet Towel with Solution made of Mixture of Viscose and Polyester |
| **Color** | White |
| **Odor** | Special perfume |
| **pH value** | 4.5-5.5 (25 °C, direct) |
| **Odor threshold** | No data available |
| **Melting point/melting range** | No data available |
| **Boiling point/boiling range** | No data available |
| **Flash point** | No data available |
| **Evaporation rate** | No data available |
| **Flammability** | No data available |
| **Upper/lower flammability or explosive limits** | No data available |
| **Auto ignition temperature** | No data available |
| **Danger of explosion** | No data available |
| **Vapor pressure** | No data available |
| **Vapor density** | No data available |
| **Relative density** | No data available |
| **Solubility in/Miscibility with water** | No data available |

## 10. STABILITY AND REACTIVITY

| | |
|---|---|
| **Reactivity** | No data available |
| **Chemical stability** | Stable under recommended storage conditions. |
| **Conditions to avoid** | None known based on information supplied |
| **Incompatible materials** | None known |
| **Hazardous decomposition products** | None known |

## 11. TOXICOLOGICAL INFORMATION

| | |
|---|---|
| **Skin contact** | Substance may cause slight skin irritation. |
| **Eye contact** | May cause temporary eye irritation. |
| **Inhalation** | May cause irritation of respiratory tract. |
| **Ingestion** | Ingestion may cause irritation to mucous membranes. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. |
| **Carcinogenicity** | Contains no ingredient listed as a carcinogen. |
| **Mutagenic effects** | No information available. |
| **Reproductive toxicity** | No information available. |

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity** The environmental impact of this product has not been fully investigated.
**Persistence and Degradability** No information available.
**Bioaccumulation** No data available

## 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods**
**Disposal methods** Dispose of in accordance with federal, state and local regulations.

## 14.TRANSPORT INFORMATION

**DOT** NOT REGULATED
**TDG** NOT REGULATED
**ICAO/IATA** NOT REGULATED
**IMDG/IMO** NOT REGULATED

## 15. REGULATORY INFORMATION

**US Federal Regulations**
**SARA Section 355 (extremely hazardous substances)** None
**SARA Section 313 (specific toxic chemical listings)** None
**Clean Air Act, Section 112 Hazardous Air Pollutants (HAPs)** None
**TSCA (Toxic Substances Control Act)** None

## 16. OTHER INFORMATION

**Prepared By** Eruslu Saglik Urunleri Sanayi ve Ticaret Anonim Sirketi
4. Organized Industrial Zone 83424 Street
No: 3 Şehitkamil, Gaziantep, Turkey
90-342-357-02-00
**Issuing Date** 13-Jan-2020
**Revision Date** 1-Apr-2020

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Safety Data Sheet**

# EU/EC Declaration of Conformity

**G&Y® Antibacterial Wet Wipes**

## 1. IDENTIFICATION

| | |
|---|---|
| **Product Name** | **G&Y® Antibacterial Wet Wipes** |
| **Manufacturer** | Eruslu Saglik Urunleri Sanayi ve Ticaret Anonim Sirketi |
| **Manufacturer Address** | 4. Organized Industrial Zone 83424 Street<br>No: 3 Şehitkamil, Gaziantep, Turkey |
| **Telephone** | 90-342-357-02-00 |
| **Certifications** | EU/EC Declaration of Conformity |
| **Test Report No** | Tr20200604017 |
| **Class** | CLASS 1 -STERILE |
| **Suitable for** | Hospitals and clinics, food businesses, Grocery Store, Pharmacies/Cosmetics, Schools / Institutions, Food Production, Offices, Public Restrooms, Chemical Industry |
| **Antibacterial action** | Bactericidal, Fungicidal, Virucidal effects against norovirus and Coronavirus (COVID-19) |
| **Harmonized Standards** | EN 1276:20 19, EN 13727+A2, EN 1500 :2013, EN 1275:2 006 , EN 1650+A1:2013, EN 13624:2014, EN 14476+A1 :20 19, HINI, EN 16615: 2015, EN 14476+A2 |
| **Directives and Regulations** | 2007/22/EEC COUNCIL DIRECTIVE<br>76/768/EEC COSMETICS DIRECTIVE |

## 2. HARMONIZED STANDARDS

| | |
|---|---|
| EN 1275 | Yeasticidal Activity |
| EN 1276 | Bactericidal Activity |
| EN 13624 | Evaluation of Fungicidal Or Yeasticidal Activity |
| EN 13727+A2 | Bactericidal Activity |
| EN 14476+A1 | Virucidal Efficacy |
| EN 14476+A2 | Virucidal Efficacy |
| EN 1500:2013 | Hygienic Handrub |
| EN 1650+A1 | Evaluation of Fungicidal or Yeasticidal Activity |
| EN 16615 | Bactericidal and Yeasticidal Activity |
| H1N1 | Influenza A Virus Efficacy |

# 3. PERFORMANCE CRITERIA

**Overview of (EN) standards, test conditions, and pass criteria**

This table supports the Biocidal Products Regulation, Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants, available in Volume II Efficacy Assessment and Evaluation (Parts B+C)[1].

## NOTES to the reader:

1. The tables provide an overview of available phase 2,1 and 2,2 EN standards which are applicable for testing the efficacy of disinfectant biocides. This overview is not exhaustive. For other, or more specific uses, and tests other than EN standards reference should be made to the relevant sections of the ECHA guidance.

**2. Please note that this is a simplified overview of the requirements. It can only be used as an aide to the requirements as started in the ECHA Guidance. Always check the respective sections of the Guidance for additional requirements.**

3. It should be noted that although the ECHA Guidance is mainly based on EN standards, there are some cases where there are discrepancies between the Guidance and EN tests and in such cases the ECHA Guidance should be followed as the leading guidance. Where noted these are identified in the table.

4. The reader is strongly advised to check whether there are new versions of the standards on the website of the CEN : www.cen.eu.

5. It should be noted that if tests other than CEN norms (notably when no CEN tests are available) are used, and pass criteria are available, these should be met (unless stated differently in this guidance). When the test does not provide pass criteria, the criteria below can be taken into account as guidance for what level of reduction is normally required.

6. In all cases, deviations from these norms are possible but should be justified in the application.

7. Regarding the table for PT 5, it should be noted that the text for PT 5 of the Guidance document (section 6) is only **"preliminary draft text"** and has not been reviewed or revised to address written PEG comments received. The revised version developed within the "Disinfectants Project" will undergo PEG consultation in 2017. In the meantime, the "preliminary draft text" is available to readers for information and it is for this reason that a table for PT 5 is included in this document, but this will be reviewed when Section 6 of the Guidance is reviewed.

## PROCEDURE for updating this document

This document can be updated or revised by submitting a request for review to the BPC Efficacy Working Group to the following email address: BPC- WGs@echa.europa.eu. The request should include the following:

- Describe and explain the text to be revised giving reasons and justification for the proposed changes;
- Submit proposed revised text;
- Identify table number/name and section with page numbers of text to be reviewed and revised

| Product type / micro-organism | Requirements[1] | Test required[2] | Contact time[3] | Temp (°C) | Soiling conditions[4] | Required lg reduction |
|---|---|---|---|---|---|---|
| **hygienic handrub** | | | | | | |
| bacteria | Basic requirement - 2,1 test | EN 13727 / EN 1276[5] | 30 - 60 sec[6] | 20 | clean / dirty | 5 |
| bacteria | Basic requirement - 2,2 test | EN 1500 | 30 - 60 sec[6] | skin T | none | ≥ propan-2-ol[7] |
| yeast | Basic requirement - 2,1 test | EN 13624 / EN 1650[5] | 30 - 60 sec[6] | 20 | clean / dirty | 4 |
| mycobacteria/ tuberculosis | Optional - 2,1 test | EN 14348 | 30 - 60 sec[6] | 20 | clean / dirty | 4 |
| viruses | Optional - 2,1 test | EN 14476 | 30 - 120 sec[6] | 20 | clean / dirty | 4 |
| fungal spores | Optional - 2,1 test | EN 13624/ EN 1650[5] | 30 - 60 sec[6] | 20 | clean / dirty | 4 |
| **hygienic handwash** | | | | | | |
| bacteria | Basic requirement - 2,1 test | EN 13727 / EN 1276[5] | 30 - 60 sec[6] | 20 | dirty[8] | 3 / 5[8] |
| bacteria | Basic requirement - 2,2 test | EN 1500 | 30 - 60 sec[6] | skin T | none | > control[10] |
| yeast | Basic requirement - 2,1 test | EN 13624 / EN 1650[5] | 30 - 60 sec[6] | 20 | dirty[8] | 2 / 4[9] |
| mycobacteria/ tuberculosis | Optional - 2,1 test | EN 14348 | 30 - 60 sec[6] | 20 | dirty[8] | 4 |
| viruses | Optional - 2,1 test | EN 14476 | 30 - 120 sec[6] | 20 | dirty[8] | 4 |
| fungal spores | Optional - 2,1 test | EN 13624/ EN 1650[5] | 30 - 60 sec[6] | 20 | dirty[8] | 2 / 4[9] |
| **surgical hand disinfection** | | | | | | |
| bacteria | Basic requirement - 2,1 test | EN 13727 | 2-3 min[11] | 20 | clean / dirty | 5 |
| bacteria | Basic requirement - 2,2 test | EN 12791 | 2-3 min[11] | skin T | none | ≥ propan-1-ol[12] |
| yeast | Basic requirement - 2,1 test | EN 13624 | 2-3 min[11] | 20 | clean / dirty | 4 |
| mycobacteria/ tuberculosis | Optional - 2,1 test | EN 14348 | 2-3 min[11] | 20 | clean / dirty | 4 |
| viruses | Optional - 2,1 test | EN 14476 | 2-3 min[11] | 20 | clean / dirty | 4 |
| fungal spores | Optional - 2,1 test | EN 13624 | 2-3 min[11] | 20 | clean / dirty | 4 |

## 4. NOTES on TABLES

**Overview of (EN) standards, test conditions, and pass criteria**

This table supports the Biocidal Products Regulation, Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants, available in Volume II Efficacy Assessment and Evaluation (Parts B+C)1.

[1] Requirements: basic requirements are mandatory and have to be fulfilled for authorisation of a product with this intended use. In addition, other organisms claimed are optional, i.e. if the requirements for these organisms are not fulfilled these organisms will be excluded from the claim.

[2] EN-tests are strongly advised but not mandatory. Other tests carried out according to standard guidelines are acceptable if a clear description of the test procedure (including contact time, soiling, temperature, suitable controls, log10 reduction, etc.) and justification is provided.

[3] Contact time: maximum acceptable contact times are stated, at which efficacy should be demonstrated. If a shorter contact time is stated on the label, efficacy has to be demonstrated at this shorter contact time. It is recommended to only use contact times mentioned in the EN standards as obligatory or additional contact time, to keep the robustness of the test as much as possible.

[4] Soiling conditions: low level soiling conditions are acceptable if it is stated on the label that cleaning prior to disinfection is necessary. Otherwise, and in case no prior cleaning is possible, dirty conditions have to be included in the tests.

| | |
|---|---|
| **PT 1** | For hospitals and health care:<br>Dirty 3 g/L bovine albumin + 3 ml/L sheep erythrocytes // Clean 0.3 g/L bovine albumin. |
| **PT 1** | other uses:<br>Dirty 3 g/L bovine albumin // Clean 0.3 g/L bovine albumin. |

[5] For non-medical applications. In case both types of applications are claimed, only one test has to be carried out, in which the relevant worst case test conditions (in general medical test) are included

[6] For hygienic handwash and handrub products used in **hospitals** the contact time is usually 30 seconds, for other uses the contact time is between 30 and 60 seconds (up to 120 seconds in case of virucidal activity). Please note that some EN tests were not developed for hand disinfection and therefore contact times shall be adapted.

[7] According to EN 1500 the test is passed when the mean reduction achieved by the hygienic handrub product under test is at least not inferior to that achieved by a reference handrub with propan-2-ol 60 % (v/v) (p=0.025).

[8] For handwash disinfectants it is assumed that hands will not be washed before washing with a disinfectant. Therefore, tests have to be done under dirty conditions.

[9] The required lg reduction in EN 13727 / EN 13624 is lower than in EN 1276 / EN 1650, as in EN 13727 and EN 13624 for hygienic handwash products the highest accepted concentration tested is 50%

[10] According to EN 1499 the test is passed when the mean reduction achieved by the hygienic handwash with the product under test is larger than that achieved by a specified reference hygienic handwash (unmedicated liquid soap) (p=0.01).

[11] The WHO states that for several products, scrubbing for 2-3 minutes reduces bacterial counts to acceptable levels. However, in the past, longer scrubbing times were accepted. Contact times of longer than 3 minutes, and up to 5 minutes, will only be authorised with a sound justification on the necessity of such long scrubbing times. Shorter contact times are accepted when tested at this contact time.

[12] According to EN 12791 the test is passed when the mean reduction achieved by the surgical handrub product under test is at least not inferior to that achieved by a reference handrub with propan-1-ol 60 % (v/v).

UKS ULUSLARARASI KALİTE SİSTEMLERİ VE BELGELENDİRME LTD. ŞTİ.

## EC DECLARATION OF CONFORMITY
## AT UYGUNLUK BEYANI

CE

**Üretici / Manufacturer**
Eruslu Sağlık Ürünleri San. Ve Tic. A.Ş.

**Adres / Address**
Başpınar (Organize) Osb Mh. O.S.B. 4. Bölge 83424 Nolu Cd. Eruslu Sağlık Ürünleri Sit. No:3 Şehitkamil / Gaziantep / TÜRKİYE

**Ürünün Markaları / Brands of the Product**
Sleepy, Yess Baby, Purewipes , Penguin, Baby Turco, Soft Touch, Bioderminy, Mooncare, G&Y, Sweet Baby, Freshlife, Actual, Virowall, V-TUF

**Ürün İsmi / Product Name**
ANTİBAKTERİYEL ISLAK HAVLU / ANTIBACTERIAL WET WIPES
ANTİBAKTERİYEL CEP MENDİLİ / ANTIBACTERIAL POCKET WIPES

**Sınıfı / Class**
SINIF 1 - STERİL / CLASS 1 – STERILE

**Test Rapor Numarası / Test Report No**
Tr20200604017

**Harmonize Standartlar / Harmonized Standards**
EN 1276:2019, EN 13727+A2, EN 1500:2013, EN 1275:2006, EN 1650+A1:2013, EN 13624:2014, EN 14476+A1 :2019, H1N1, EN 16615: 2015, EN 14476+A2

**Direktif ve Yönetmelikler / Directives and Regulations**
2007/22/EC KONSEY DİREKTİFİ / 2007/22/EEC COUNCIL DIRECTIVE
76/768/EEC KOZMETİK DİREKTİFİ / 76/768/EEC COSMETICS DIRECTIVE

**This Certificate is issued under the following conditions:**

1. It applies only to the above referenced models of the medical devices.
2. It does not imply that the UKS has performed any surveillance or control of their manufacture.
3. The manufacture is obligated to assure conformity of all in medical devices of the respective model to type assessed by the mean of this certificate.
4. The certificate remains valid until the manufacturing condition, the quality system or relevant legislation are changed.
5. After fulfilling of the relevant EU legislation requirements, the manufacture shall affix to each medical device, of the above referenced models, the CE-marketing according to the examples.

**Sertifika No / Certificate No:** CED-0018
**Sertifika Tarihi / Certificate Date:** 05.06.2020
**Sertifika Bitiş Tarihi / Certificate Exp. Date:** 04.06.2021

Genel Müdür
General Manager



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