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|-------------------------------------|-----------------------|-------------------|--------------------|----------------------|
| <b>KAFGRUP</b><br>SAĞLIK HİZMETLERİ | <b>EC DECLARATION</b> |                   |                    |                      |
|                                     | <b>Document No</b>    | <b>Issue Date</b> | <b>Revision No</b> | <b>Revision Date</b> |
|                                     | TD. 04.51             | 10.06.2019        | 06                 | 05.03.2024           |




### EC DECLARATION OF CONFORMITY

#### Medical Devices Directive 93/42/EEC

|                                  |   |   |
|----------------------------------|---|---|
| <b>Company Name</b>              | : | KAF GRUP SAĞLIK HİZMETLERİ İNŞ. SAN. TİC. LTD. ŞTİ  |
| <b>Authorized Person / Title</b> | : | Gökmen Aydin / General Manager  |
| <b>Head Office Address</b>       | : | Atakent Mahallesi 221 Sk. No:3A Rota Office A Blok Kat:14 D:83<br>Küçükçekmece/İstanbul/Türkiye |
| <b>Production Address</b>        | : | Bardakçı Mah. Teknokent Sk. No:3 Tuşba/VAN/Türkiye  |
| <b>Phone Number</b>              | : | 0212 471 42 00  |
| <b>Website</b>                   | : | www.kafgrup.com   |
| <b>E-Mail</b>                    | : | info@kafgrup.com  |
| <b>Brand Information</b>         | : | WANCARE   |

as, the models and GMDN Codes of our Onesurface Alcohol-Free Fast Acting Spray Disinfectant For Medical Equipments, Onespray Alcohol-Based Fast Acting Spray Disinfectant For Medical Equipments, Onesurface Wipes Alcohol- Free Fast Acting Disinfectant Wipes For Medical Devices, Onespray Wipes Alcohol-Based Fast Acting Disinfectant Wipes For Medical Devices products specified in the TD.04.22 **Product Model and GMDN Code Table** and below;

| REFERENCE CODE | PRODUCT NAME   | ACTIVE SUBSTANCE                      | VOLUME | GMDN CODE | CLASS |
|----------------|--|---------------------------------------|--------|-----------|-------|
| KAF G20-1      | Onespray Alcohol-Based Fast Acting Spray Disinfectant For Medical Equipments | Ethyl Alcohol, Isopropyl Alcohol, QAC | 750 ml | 47631     | Ila   |
| KAF G20-2      | Onespray Alcohol-Based Fast Acting Spray Disinfectant For Medical Equipments | Ethyl Alcohol, Isopropyl Alcohol, QAC | 1 L    | 47631     | Ila   |
| KAF G20-3      | Onespray Alcohol-Based Fast Acting Spray Disinfectant For Medical Equipments | Ethyl Alcohol, Isopropyl Alcohol, QAC | 5 L    | 47631     | Ila   |
| KAF G21-1      | Onesurface Alcohol-Free Fast Acting Spray Disinfectant For                   | Hydrogen Peroxide+QAC                 | 750 ml | 47631     | Ila   |

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|           | Medical Equipments   |                                       |         |       |     |
|-----------|--|---------------------------------------|---------|-------|-----|
| KAF G21-2 | Onesurface Alcohol-Free Fast Acting Spray Disinfectant For Medical Equipments    | Hydrogen Peroxide+QAC                 | 1 L     | 47631 | Ila |
| KAF G21-3 | Onesurface Alcohol-Free Fast Acting Spray Disinfectant For Medical Equipments    | Hydrogen Peroxide+QAC                 | 5 L     | 47631 | Ila |
| KAF G35-1 | Onespray Wipes Alcohol-Based Fast Acting Disinfectant Wipes For Medical Devices  | Ethyl Alcohol, Isopropyl Alcohol, QAC | 100 Pcs | 58077 | Ila |
| KAF G35-2 | Onespray Wipes Alcohol-Based Fast Acting Disinfectant Wipes For Medical Devices  | Ethyl Alcohol, Isopropyl Alcohol, QAC | 150 Pcs | 58077 | Ila |
| KAF G35-3 | Onespray Wipes Alcohol-Based Fast Acting Disinfectant Wipes For Medical Devices  | Ethyl Alcohol, Isopropyl Alcohol, QAC | 200 Pcs | 58077 | Ila |
| KAF G36-1 | Onesurface Wipes Alcohol-Free Fast Acting Disinfectant Wipes For Medical Devices | Hydrogen Peroxide+QAC                 | 100 Pcs | 58077 | Ila |
| KAF G36-2 | Onesurface Wipes Alcohol-Free Fast Acting Disinfectant Wipes For Medical Devices | Hydrogen Peroxide+QAC                 | 150 Pcs | 58077 | Ila |
| KAF G36-3 | Onesurface Wipes Alcohol-Free Fast Acting Disinfectant Wipes For Medical Devices | Hydrogen Peroxide+QAC                 | 200 Pcs | 58077 | Ila |

|                            |                         |  |
|----------------------------|-------------------------|--|
| EN ISO 13485:2016/A11:2021 | EN 62366-1:2015/A1:2020 | EN ISO 20417:2021                              |
| EN 14476:2013+A2:2019      | EN 14885:2022/AC:2023   | EN 13624:2021                                  |
| EN ISO 14971:2019/A11:2021 | EN ISO 15223-1:2021     | ASTM F1980-16                                  |
| EN 13727:2012+A2:2015      | TS 10340:1992           | EN 17126: 2018                                 |
| EN 2871-2:2010             | EN 16615:2015           | EN 14348:2005                                  |
| TS 6773:1989               | EN 13704:2018           | European Pharmacopoeia (Ph. Eur.) 11th Edition |

Manufactured to harmonized standards, and we declare that it complies with the provisions of the

**Medical Device Directive 93/42/EEC Annex II excluded (4)**

**Full Quality Assurance Certificate**

**Class Ila**

**(93/42/EC Annex IX, Rule 15 )**

|                         |   |
|-------------------------|---|
| <b>GMND Code</b>        | 47631- Quaternary (quaternary) ammonium compound device disinfectant/cleaner  |
| <b>GMDN Description</b> | Liquid substance that contains chemical cleaners and quaternary ammonium compounds as primary disinfection agent, used to clean and disinfect medical devices (eg, surgical or dental instruments). To achieve disinfection, the medical device is typically immersed in the agent for a specified period of time or the agent is applied manually to the medical device. This device cannot be reutilized after application. |

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|                         |  |
|-------------------------|--|
| <b>GMND Code</b>        | 58077- Medical device cleaning/disinfection wipe   |
| <b>GMDN Description</b> | Pre-treated fabric designed to clean and disinfect the surfaces of medical devices and instruments by wiping for individual patient use. This fabric is impregnated with a solution of detergent(s) and antimicrobial agent(s), and is designed to reduce the amount of soiling and microbial contamination on the surfaces of medical devices and instruments; This product is not designed to be the main form of instrument cleaning and disinfection. It is a disposable device. |

|                                     |   |   |
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| <b>Notified Body</b>                | : | TÜRK STANDARDLARI ENSTİTÜSÜ   |
| <b>Notified Body Address</b>        | : | Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA/TÜRKİYE  |
| <b>Notified Body Identity No</b>    | : | 1783  |
| <b>Certificate No</b>               | : | 1783-MDD-211  |
| <b>Issue Date of Certificate</b>    | : | 17.05.2021  |
| <b>Validity Date of Certificate</b> | : | 26.05.2024  |
| <b>CE Marking Start Date</b>        | : | 17.05.2021  |
| <b>Company Declaration Date</b>     | : | 05.03.2024  |
| <b>Place of Declaration</b>         | : | İSTANBUL-TÜRKİYE  |
| <b>Declarant</b>                    | : | Gökmen Aydin / GENEL MANAGER  |
| <b>Approval</b>                     | : | <p style="text-align: center;">KAF GRUP SAĞLIK HİZMETLERİ<br/>İNŞAAT SANAYİ VE TİC.LTD.ŞTİ.<br/>Atakent Mh. 22. Sk. No:3A Rota Office<br/>A Blok D.83/11 Çekirgeci / İSTANBUL<br/>Tel: 0212 471 42 00 Fax: 0212 471 42 01<br/>Halkalı V.D: 486 050 3864</p> |