TECHNICAL UNIVERSAL VERIFICATION
BELGELENDİRME VE EĞİTİM HİZ. LTD. ŞTİ.

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Test Adı/Testing Name: **DERMAL İRRİTASYON & DERMAL IRRITATION**	Rapor Numarası/Report No	**KBYU0005/2021-03/BYU/1451**

TESTING LABORATORY ISO/IEC 17025:2017 NAC-003-TL

NAC-003-TL

** This report ISO 17025: has been prepared within the scope o general conditions for the competence of testing and calibration laboratories

BİYOUYUMLULUK TEST LABORATUVARI
BIOCOMPATIBILITY TESTING LABORATORY

FİRMA ADI/COMPANY NAME:	**DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.**
ADRES/ADDRESS:	**İSTANBUL VİZYON PARK OFİS BLOKLARI YENİBOSNA MERKEZ MAH. 29 EKİM CAD. NO:3 PLAZA 1 K:8 NO:84 BAHÇELİEVLER – İSTANBUL - TURKEY**
TESTİN ADI/TESTING NAME:	**DERMAL IRRITATION**
TEST STANDARDI/TEST STANDARD:	**TS EN ISO 10993-10: 2014-02**
TİCARİ MARKA (VARSA)/COMMERCIAL BRAND (IF YOU HAVE):	**-**
ÜRÜN ADI/PRODUCT NAME:	**FFP2 NR DISPOSABLE VALVE FACE MASK**
NUMUNE KAYIT NO/SAMPLE REGİSTRATİON NO:	**KBYU0014/2021**
NUMUNE LOT NUMARASI/LOT NUMBER OF SPECIMENS:	**DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR**
NUMUNE SAYISI/NUMBER OF SPECIMEN:	**6**
TEST BAŞLAMA TARİHİ/TEST START DATE:	**02.03.2021**
TEST BİTİŞ TARİHİ/TEST END DATE:	**05.03.2021**
RAPOR TARİHİ/REPORT DATE:	**22.03.2021**
KULLANILAN CİHAZLAR/USED DEVICES:	**-**
EA TANIMLAMASI/EA DESCRIPTION:	**Asia Pasific Accreditation Association (APAC) ISO/IEC 17025: 2017 CABs National Accreditation Center (NAC) by accredited the general requirements for the adequacy of the test and calibration laboratoires standard for the recognition of test report. It proves the traceability to national measurement standards that are defined in the International System of Units (SI), realizing the units.**

BİYOUYUMLULUK TEST SORUMLUSU	**VETERİNER HEKİM**	**TECHNİCAL UNİVERSAL VERİFİCATİON**
BİYOKİMYAGER	**SONER AKTEMUR**	
YEŞİM ÖZKUL		

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ISO 10993-10 STANDARD

DERMAL IRRITATION TEST

TEST REQUESTED INSTITUTION AND SPECIMEN NAME

DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.

FFP2 NR TEK KULLANIMLIK VALFSİZ YÜZ MASKESİ

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1. GENERAL INFORMATION ABOUT THE TEST

Test Name and Guide	TS EN ISO 10993-10 Biological evaluation of medical devices chapter 10: Tests standard for irritation and skin sensitivity
Test Requesting Institution	**DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.**
Test Report Number	KBYU0005/2021-03/BYU/1451
Test Start Date	02.03.2021
Test Ending Date	05.03.2021
Test Reporting Date	22.03.2021
Purpose	The test was intended to evaluate the potential of the sample described below to cause dermal irritant effects.

2. INFORMATION ABOUT THE SPECIMEN

Specimen Acceptance Date and Time	28.01.2021
Specimen Recording Number	KBYU0014/2021
Specimen Lot Number	DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR
Name of Specimen	FFP2 NR DISPOSABLE VALVE FACE MASK
Number of Specimen	6
Specimen Taken Moment Receive	SOLID
Way the Specimen Was Brought	HAND BY RECEİVE
Information About Witness Specimen	Preserve TECHCERT laboratory for 1 year

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3. INFORMATION ABOUT TEST ANIMALS TAKEN IN THE TEST

Species	Rabbit
Kind	New Zealand Rabbit
Source	Kobay DHL A.Ş.
Gender	Male
Weight Range	2-2,5 kg
Age	Young Adult
Familiarization Period	5 days
Number of Animal Used	3 piecies

4. INFORMATION ABOUT USED CHEMICAL AND MEDIUM

Test Animals Maintenance	Chapter 2: Requirements for Animal Welfare are made in accordance with its standards.
Forage	Ad-libitum is done feeding.
Water	Water, be given ad-libitum as suitable drinkers.
Micro Maintenance Conditions	Each test animal was identified and placed in appropriate cages.
Macro Maintenance Conditions	Provides 12 hours of night and 12 hours of daytime environment; %30-70 damp and 17- 23 ºC environment is provided. temperature and damp are checked instant daily.
Test Team	Tests are carried out by trained and suitably qualified people.
Test Animal Selection	Healthy, disease-free and under the supervision of a veterinarian It was selected by passing.

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5. INFORMATION ABOUT THE TEST METHOD

TS EN ISO 10993-10 Biological evaluation of medical devices chapter 10: According to the requirements of the test standard for irritation and skin sensitivity, the maintanence conditions of the test animals used in the test were carried out by considering ISO 10993-2 and the preparation of the specimen used in the test and the reference materials ISO-10993-12 standards.
Dermal Irrıtation Tests; Subsequently the skin application, the animals were observed at different time intervals and the results were evaluated.

6.DERMAL APPLICATION

Specimen; Prepared according to the "Standard surface areas and extract liquid volumes chart" in the standard of TS EN ISO 10993-12 "Specimen Preparation and Reference Materials". As a positive control; Sodium lauryl sulfate (SLS), previously known to have an irritant effect, has been determined. As a negative control; Serum Physiological, previously known to have no irritant effect.

Test and control specimen were applied to the back region of the test animals, whose weights were recorded in Table 1, topically for 4 hours to the skin in the regions and volumes indicated in Figure 1. At the end of this period, bandages were opened, samples were taken and the applied areas were marked. Test materials remaining in the area were washed with warm water. After the procedure the test zones were observed at the 1st,24th,48th and 72nd hours and the specimen were evaluated by considering the criteria in table 2. The evaluation results that should be given according to the score obtained are recorded in Table 3.

Test start date	02.03.2021
Test ending date	05.03.2021

TS EN ISO 10993-10 Biological evaluation of medical devices chapter 10: Biocompatibility test was applied according to the test standard for irritation and skin sensitivity. Animals TS EN 10993-2: 2006 Biological Evaluation of Medical Devices - Part 2: It has been prepared in accordance with the principles of Requirements for Animal Welfare. The test was carried out so as to evaluate the sensitizing potential of the specimen.

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Solution preparation date	28.02.2021
Solution preparation know how	Chapter 12: According to specimen preparation and reference materials standard; X If specimen solid; "The specimen was prepared by keeping the specimen at 37°C for 72 hours according to the chart of standard surface areas and extract liquid volumes. Subsequently, it was impregnated with a 25x25 mm four-layer gauze and applied to the skin. ○ If specimen liquid; directly impregnated with 25x25 mm four-layer gauze and applied to the skin. Serum Physiological impregnated with 25x25 mm four-layer gauze was used as a control specimen

CRANIAL TIP

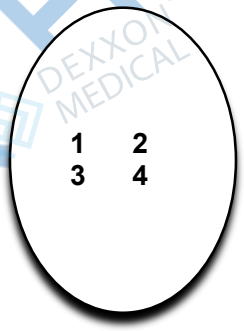

FIGURE 1

CAUDAL TIP