
	<b>TECHNICAL UNIVERSAL VERIFICATION</b> <b>BELGELENDİRME VE EĞİTİM HİZ. LTD. ŞTİ.</b> Macun Mahallesi ATB İş Merkezi A Blok No: 3 Yenimahalle / ANKARA Tel: +90 312 231 82 02 & E-Mail: <a href="mailto:info@techcert.com.tr">info@techcert.com.tr</a> & <a href="http://www.techcert.com.tr">www.techcert.com.tr</a>	 TESTING LABORATORY ISO/IEC 17025:2017 NAC-003-TL NAC-003-TL
Test Adı/Testing Name: <b>SENSİTİZASYON &amp; SENSITIZATION</b>	Rapor Numarası/Report No	<b>KBYU0005/2021- 03/BYU/1450</b>

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



**BİYUYUMLULUK TEST LABORATUVARI**  
**BIOCOMPATIBILITY TESTING LABORATORY**

<b>FİRMA ADI/COMPANY NAME:</b>	DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.
<b>ADRES/ADDRESS:</b>	İSTANBUL VİZYON PARK OFİS BLOKLARI YENİBOSNA MERKEZ MAH. 29 EKİM CAD. NO:3 PLAZA 1 K:8 NO:84 BAHÇELİEVLER – İSTANBUL - TURKEY
<b>TESTİN ADI/TESTING NAME:</b>	SENSİTİZASYON & SENSITIZATION
<b>TEST STANDARDI/TEST STANDARD:</b>	TS EN ISO 10993-10: 2014-02
<b>TİCARİ MARKA (VARSA)/COMMERCIAL BRAND (IF YOU HAVE):</b>	-
<b>ÜRÜN ADI/PRODUCT NAME:</b>	FFP2 NR DISPOSABLE VALVE FACE MASK
<b>NUMUNE KAYIT NO/SAMPLE REGISTRATION NO:</b>	KBYU0014/2021
<b>NUMUNE LOT NUMARASI/LOT NUMBER OF SPECIMENS:</b>	DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR
<b>NUMUNE SAYISI/NUMBER OF SPECIMEN:</b>	6
<b>TEST BAŞLAMA TARİHİ/TEST START DATE:</b>	02.02.2021
<b>TEST BİTİŞ TARİHİ/TEST END DATE:</b>	02.03.2021
<b>RAPOR TARİHİ/REPORT DATE:</b>	22.03.2021
<b>KULLANILAN CİHAZLAR/USED DEVICES:</b>	-
<b>EA TANIMLAMASI/EA DESCRIPTION:</b>	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 laboratories 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.

<b>BİYUYUMLULUK TEST SORUMLUSU</b> <b>BİYOKİMYAGER</b> <b>YEŞİM ÖZKUL</b> 	<b>VETERİNER HEKİM</b> <b>SONER AKTEMUR</b> 	<b>TECHNICAL UNIVERSAL VERIFICATION</b> 
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**BİYUYUMLULUK TEST LABORATUVARI**  
**BIOCOMPATIBILITY TESTING LABORATORY**



**CONTENTS**

- 1. INFORMATION ABOUT THE TEST**
- 2. INFORMATION ABOUT THE SPECIMEN**
- 3. INFORMATION ABOUT TEST ANIMALS TAKEN IN THE TEST**
- 4. INFORMATION ABOUT LABORATORY CONDITIONS**
- 5. INFORMATION ABOUT THE TEST METHOD**
- 6. TEST**
- 7. INTRA SKIN INDUCING PHASE**
- 8. SURFACE (TOPICAL) INDUCING PHASE**
- 9. STIMULATION PHASE**
- 10. RESULT**
- 11. RECORDS**
- 12. REFERENCES**

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**SENSITIZATION TEST RESULT REPORT**

**NAME OF TEST**

**ISO 10993-10 STANDARD**

**SENSITIZATION TEST**

**TEST REQUESTED INSTITUTION AND SPECIMEN NAME**



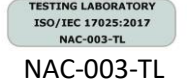
**DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.**

**FFP2 NR DISPOSABLE VALVE FACE MASK**

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**BİYUYUMLULUK TEST LABORATUVARI**  
**BIOCOMPATIBILITY TESTING LABORATORY**

**1.GENERAL INFORMATION ABOUT THE TEST**

Test Name and Guide	TS EN ISO 10993-10:2014 Biological evaluation of medical devices Chapter 10: Standard for test for irritation and skin sensitivity
Test Requesting Institution	<b>DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.</b>
Test Report Number	KBYU0005/2021-03/BYU/1450
Test Start Date	<b>02.02.2021</b>
Test Ending Date	<b>02.03.2021</b>
Test Reporting Date	<b>22.03.2021</b>
Purpose	The test is intended to assess the sensitizing potential of the specimen described below



**2.INFORMATION ABOUT THE SPECIMEN**

Sample Acceptance Date and Time	28.01.2021
Sample Registration Number	KBYU0014/2021
Sample Lot Number	DEXXON MEDICAL DXNMD-NRFMO4 FFP2 NR
Sample Name	FFP2 NR TEK KULLANIMLIK VALFSİZ YÜZ MASKESİ
Number of Samples	6
Status at the Time of Sampling	KATI / SOLID
Delivery Method of the Sample	HAND BY RECEİVE
Witness Sample Information	Preserve TECHCERT laboratory for 1 year

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### BİYUYUMLULUK TEST LABORATUVARI BIOCOMPATIBILITY TESTING LABORATORY

#### 3. INFORMATION ABOUT THE TEST ANIMALS TAKEN IN THE TEST

Kind	Guinea Pig
Family	Dunkin Hartley
Source	Kobay DHL A.Ş.
Gender	Male
Weight Source	400-500 gr
Age	10-12 week
Familiarization Period	5 days
Number of Animals Used	15 pieces



#### 4. INFORMATION ABOUT LABORATORY CONDITIONS

Test Animal Maintenance	The animal used in the tests are made in accordance with the Biological Evaluation of Medical Devices-Part 2 Requirements for Animal Welfare 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 23 °C environment is provided. temperature and damp are checked instant daily.
Test Team	Tests are carried out by trained and suitably qualified people
Selection of Test Animals	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

Sensitization Tests; TS EN ISO 10993-10 Biological Evalaulation of Medical Devices-Chapter 10: According to the requirements of the test standard for irritation and skin sensitivity, the maintenance 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.
Sensitization Tests; Intradermal Induction Phase, Superfical Induction Phase and subsequently the Stimulation Phase, observing the animals and evaluating finished the results.



### 6. TEST

Test start date	02.02.2021
Test ending date	02.03.2021
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 – Chapter 2: It has been prepared in accordance with the principles of Requirements for Animal Welfare. The test was carried out in order to evaluate the sensitizing potential of the specimen	
Solution preparation date	31.01.2021 – 02.02.2021
Solution preparation know how	Chapter 12: According to specimen preparation and reference materials standard; <input checked="" type="checkbox"/> 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.

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## BİYUYUMLULUK TEST LABORATUVARI BIOCOMPATIBILITY TESTING LABORATORY

### CRANIAL TIP



Figure 1 – Test Group

### CAUDAL TIP

Figure 2 – Control Group

Table 1: Weight table at the end of the test belonging to the test animals

TEST GROUP	1	2	3	4	5	6	7	8	9	10
Guinea pig no										
Weights at the begenning of the test*	467	458	472	469	455	477	433	441	452	473
Weights at the end of the test	499	491	499	494	484	508	463	473	483	507
<b>CONTROL GROUP</b>										
Guinea pig no	1	2	3	4	5					
Weights at the begenning of the test*	456	450	463	468	445					
Weights at the end of the test	483	479	492	494	476					

\*300-500gr must be

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