
	TECHNICAL UNIVERSAL VERIFICATION BELGELENDİRME VE EĞİTİM HİZ. LTD. ŞTİ. Macun Mahallesi ATB İş Merkezi A Blok No: 3 Yenimahalle / ANKARA Tel: +90 312 231 82 02 & E-Mail: info@techcert.com.tr & www.techcert.com.tr	 TESTING LABORATORY ISO/IEC 17025:2017 NAC-003-TL NAC-003-TL
Test Adı/Testing Name: SENSİTİZASYON & SENSITIZATION	Rapor Numarası/Report No	KBYU0005/2021- 03/BYU/1448



** 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

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 BAĞÇELİEVLER – İSTANBUL - TURKEY
TESTİN ADI/TESTING NAME:	SENSİTİZASYON & SENSITIZATION
TEST STANDARDI/TEST STANDARD:	TS EN ISO 10993-10: 2014-02
TİCARİ MARKA (VARSA)/COMMERCIAL BRAND (IF YOU HAVE):	-
ÜRÜN ADI/PRODUCT NAME:	FFP3 NR DISPOSABLE VALVE FACE MASK
NUMUNE KAYIT NO/SAMPLE REGISTRATION NO:	KBYU0015/2021
NUMUNE LOT NUMARASI/LOT NUMBER OF SPECIMENS:	DEXXON MEDİKAL DXNMD-NRFM05 FFP3 NR
NUMUNE SAYISI/NUMBER OF SPECIMEN:	6
TEST BAŞLAMA TARİHİ/TEST START DATE:	02.02.2021
TEST BİTİŞ TARİHİ/TEST END DATE:	02.03.2021
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 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.

BİYUYUMLULUK TEST SORUMLUSU BİYOKİMYAGER YEŞİM ÖZKUL	VETERİNER HEKİM SONER AKTEMUR	TECHNICAL UNIVERSAL VERIFICATION
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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.

FFP3 NR DISPOSABLE VALVE FACE MASK

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1.GENERAL INFORMATION ABOUT THE TEST

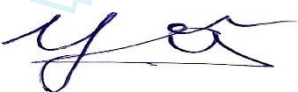
Test Name and Guide	TS EN ISO 10993-10:2014 Biological evaluation of medical devices Chapter 10: Standard for test for irritation and skin sensitivity
Test Requesting Institution	DEXXON MEDICAL/DEXXON ENERJİ SAN VE TİC. A.Ş.
Test Report Number	KBYU0005/2021-03/BYU/1448
Test Start Date	02.02.2021
Test Ending Date	02.03.2021
Test Reporting Date	22.03.2021
Purpose	The test is intended to assess the sensitizing potential of the specimen described below



2.INFORMATION ABOUT THE SPECIMEN

Numune Kabul Tarihi ve Saati	28.01.2021
Numune Kayıt Numarası	KBYU0015/2021
Numune Lot Numarası	DEXXON MEDİKAL DXNMD-NRFM05 FFP3 NR
Numune Adı	FFP3 NR TEK KULLANIMLIK VALFSİZ YÜZ MASKESİ
Numune Sayısı	6
Numune Alındığı Sıradaki Durumu	KATI / SOLID
Numunenin Getiriliş Şekli	HAND BY RECEİVE
Şahit Numune Bilgisi	Preserve TECHCERT laboratory for 1 year

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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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Yes

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BIOCOMPATIBILITY TESTING LABORATORY

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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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 beginning of the test*	485	419	462	473	444	452	459	456	431	429
Weights at the end of the test	516	448	491	504	472	481	492	485	461	461
CONTROL GROUP										
Guinea pig no	1	2	3	4	5					
Weights at the beginning of the test*	427	411	401	436	431					
Weights at the end of the test	459	439	431	463	461					

*300-500gr must be

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