

Consultancy and Laboratory Services for Biomedical Quality

# In Vitro Skin Irritation on Reconstructed Human Epidermis Test Method (according to OECD 439)

## REPORT N. 00362-21 Rev. 00

## Customer:

IDEANTIS SRL VIALE MONTE NERO 80 - 20135 - MILANO

## TIME SCHEDULE

Acceptance N.:	20-7998
Samples receiving date:	26/11/2020
Start test date:	10/12/2020
End test date:	15/01/2021
Coronati Consulting Operator:	Dr. C. Pellegrini

## **TEST MANAGEMENT**

Coronati Consulting srl Via L. Gavioli, 3 I-41037 Mirandola (MO) Certified ISO 9001/ ISO 13485 The test was performed at ABICH srl; Via 42 Martiri 213/B I-28924-Verbania (VB) Italia

## **REFERENCE DOCUMENTS**

OECD Guideline for the testing of chemicals. No. 439: In vitro Skin Irritation: Reconstructed Human Epidermis Test Method. Test Guideline as adopted (2019).

## **TEST SAMPLE IDENTIFICATION**

Name:	Maskèdra
Sample Typology:	Mascherina chirurgica
Composition:	poliuretano+poliammide12+Spunbond+Melt blown+natural rubber+poliestere
Code (REF):	N/A
Batch:	001
Manufacturing date:	ottobre 2020
Expiry date:	Non applicabile
Sterilization Method:	Not sterile
Sterilization Batch:	N/A
Sterilization Date:	N/A
Sterilization Unit:	N/A

The information concerning the test sample were provided by the Customer. All data related to the test sample are under the responsibility of the Customer and have not been verified by the test laboratory.

Issue Date	Rev.	Change Description	Prepared by Dr. C. Pellegrini (Laboratory Technician)	Verified and Approved by Dr. Renzo Giovanni Coronati (Managing Director Laboratory)	
22/01/2021	00	First Issue	ana telepini	Planenst-	
This test report is digitally signed by Dr. Renzo Giovanni Coronati. The digital signature has legal value according to Italian D. Lgs. 82/2005 and subsequent amendments.					
The sampling is performed by the Customer. The test results relate only to the test sample as received.					

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MRap 120-03 Rev.00 dated 10/07/2020

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## PROCEDURE

All procedure is reported in Annex 01.

## RESULTS

The results are reported in Annex 01.

## CONCLUSIONS

On the basis of the results, the sample "Maskèdra" is NOT A SKIN IRRITANT.

#### **RECORD FILING**

An original copy of the report No. REL/0061 Rev. 01/2021/IRRC/ELB is available at Coronati Consulting.

#### ANNEXES

Annex 01: ABICH S.r.I. Final Report Nº. REL/0061Rev.01/2021/IRRC/ELB

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