

SC ALISON HAYES (ROMANIA) SRL  
Soseaua Bucuresti-Buzau Km. 55,2  
Urziceni-Ialomita  
Romania  
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**DECLARATION OF CONFORMITY****MEDICAL SURGICAL FACE MASK WITH TIE**

No / Date                      **246/ July 2021**  
Version/ Ref                      **AH-DM10-BLACK-T**  
Type                                **I**  
Brand                               **SYNEK**  
Producer                         **SC ALISON HAYES ROMANIA SRL**  
SRN No                            **RO-MF-000004583**  
Adresă                            **Bucuresti – Buzau Km 55.2, Urziceni, Jud Ialomita , postal code 925300, FISCAL code: RO5222849 C.U.I: J21/291/1997**  
Tel/Fax                            **0372/439100**  
UDI-DI

Name of Medical Device,Col, Type	Ref	UDI -DI
<b>Medical Surgical Face Mask with Ties ,Black, Type I</b>	<b>AH-DM10-BLACK-T</b>	<b>5944756900267</b>

Clasificare                      **Class I ,according with Rule 1 from Anexa VIII , Reg (UE) 2017/745 regarding to Medical Devices**  
Lot no:                            **99-290721-02**  
Production date:                **5 AUG 2021**  
Valability :                       **5 years from the production date**

We declare under our sole responsibility that the product mentioned above meets the requirements of **Regulation (EU) 2017/745** on Medical Devices.

Conformity assessment procedure: Annex II and Annex III to **Regulation (EU) 2017/745** on medical devices

Applicable standards:

- The product is designed and manufactured under Quality Management System- **ISO 13485**
- Product Manufactured and tested in accordance with **SR EN 14683 + AC\_2019**

Emitted at Alison Hayes (Romania) SRL

Date: 28.07.2021

Authorized Signature

General Manager  
Corina Liana Stoica

