

SC ALISON HAYES (ROMANIA) SRL  
Soseaua Bucuresti-Buzau Km. 55,2  
Urziceni-Ialomita  
Romania  
Tel :0372/439100  
Email:medical@alisonhayes.com

**DECLARATION OF CONFORMITY****MEDICAL SURGICAL FACE MASK WITH TIES**

No / Date 241/ July 2021  
Version/ Ref AH-DM12-BLUE-T  
Type IIR  
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
Medical Surgical Face Mask with Ties ,Blue, Type IIR	AH-DM12-BLUE-T	5944756900212

Clasificare Class I ,according with Rule 1 from Anexa VIII , Reg (UE) 2017/745 regarding to Medical Devices  
Lot no: :99-271120-03  
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

Authorized Signature

Date: 28.07.2021

General Manager  
Corina Liana Stoica

