



**Declaration of Conformity  
according  
EU MDR 2017/745**

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**Declaration of Conformity for  
Protective Sleeves made of Polymeric Gel**

Elbow Sleeve – Size M, S, XS

Arm Sleeve – Size M, S, XS

Heel Sleeve – Size M, S

Shin Sleeve – Size M, S, XS

Ear Sleeve – Size Standard

Neck Sleeve – Size Universal

Padding Sleeve – Size 18 mm, 25 mm, 30 mm, 36 mm

**EMDN-Code: M03030202**

**UMDNS-Code: 11-326**

Registration Number at German Competent Authority/DIMDI:

**DE/CA70/40838-236571**

**manufactured by:**

SUAVEPIE SAIC


Falcón Ramón 2232, Ciudad de Buenos Aires 1406, Argentina

are classified as a medical device class 1 according to Annex VIII, Rule 1 of MDR 2017/745 and are manufactured following the regulations of MDR 2017/745 and under GMP conditions according to ANMAT Directive 7425/13. The Essential Requirements of Annex I of MDR 2017/745 are fulfilled.

Conformity Assessment Procedure: MDR 2017/745  
Classification: **Class 1**, Annex VIII, Rule 1  
EAR Mandate assigned to: MT Promedt Consulting GmbH  
66386 St. Ingbert, Germany  
DE-AR-000000085

This statement of conformity is valid in connection with the release document for the respective batch of the produced devices.

Date: 26.05.2021

  
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Signature/ Function  
MANAGING DIRECTOR