



# Quality System Approval Certificate

## Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated  
Notified Body, (identification number 0050), for the purposes of the European Communities  
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

**APPROVES THE QUALITY SYSTEM APPLIED BY**

### **SteriPack USA, LLC**

**4255 S. Pipkin Road  
Lakeland  
FL 33811  
USA**

*to the Product Family*

### **Sterile Nasopharyngeal Swab**

### **GMDN Code: 57940**

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices Annex V.  
The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of  
Conformance for this product family is hereby authorised.*

<b>Registration Number:</b>	<b>252.1252</b>
<b>Original Approval:</b>	<b>23 September 2020</b>
<b>Last Amended on:</b>	<b>29 September 2020</b>
<b>Remains valid until:</b>	<b>26 May 2024</b>

**Signed:**

Approved by:  
Dr. Caroline Dore Geraghty  
Director, Medical Devices

Approved by:  
Dr. Elaine Darcy  
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.  
Details of the current product range and operational locations included within the scope of this approval can be obtained from NSAI  
National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**