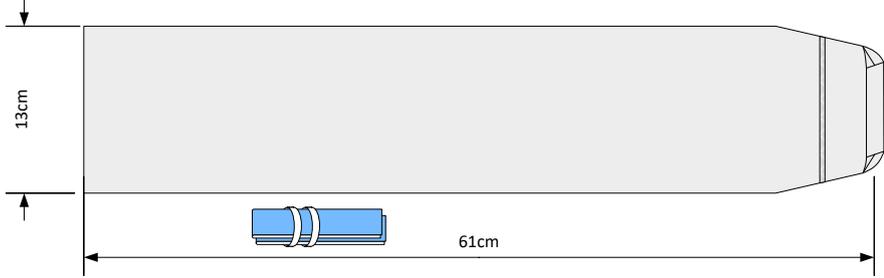
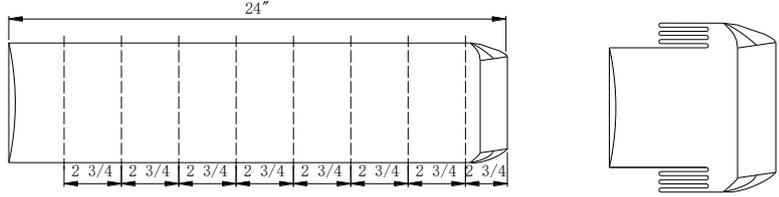


Code	E6346
GTIN code unit	06975085704706
GTIN code inner case	16975085704703
GTIIN code outer case	26975085704700
Custom Code	3926 90 92 90
General Product Description	Probe Cover, VIP film, Gel and El. bands 13x61cm - 5"x24"
Packaging	Sterile Pouch, three Inner Case with 30 units, Outer Case 90 units
Quality Requirements	EU Quality Assurance Certificate (MDR) Pudiant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A (Class I Devices in sterile condition, with measuring function or reusable surgical instruments)
Sterilization	EN ISO 11135:2014 "Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
Raw Material used	<ul style="list-style-type: none"> • TPE-Film transparent, 50 gsm • Adhesive Tape • Ultrasound Gel (1) • Latex Free Elastic Bands (2)
Diagram	

	 <div data-bbox="900 775 1166 1339" style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">exact[®] MEDICAL</p> <p style="text-align: center;">Sterile GEL</p> <p>REF E6599 LOT SJ10031016</p> <p>02-2019</p> <p>Rx 10° C / 50° F - 35° C / 98° F</p> <p>Contact medium for Ultrasonic and Electrical Transmission Gel 20 ML</p> <p>Exact Medical Manufacturing www.exactmm.com info@exactmm.com</p> <p>STERILE R  </p> <p>Unit Pouch is guaranteed sterile unless opened or damaged</p> <p style="text-align: center;">CE 1014</p> </div>
<p>Folding</p>	

<p>Manufacturing</p>	<p>According to ISO 13485:2012 + AC:2012 Medical Devices – Quality Management Systems – Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009) DIN EN ISO 13485:2012</p>
<p>Propriety and Confidentiality</p>	<p>The information contained within this document is the sole property of Exact Medical Manufacturing and reproduction in part or as a whole without the written permission of Exact Medical is prohibited.</p>
<p>Date</p>	<p>Tuesday, July 12, 2022</p>
<p>Certification and approval</p>	<p>Thijs van den Hoven, Director</p>