

# Genio® AC XXXX

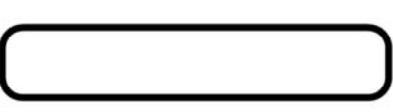
Activation Chip for treatment of  
moderate to severe OSA

**Nyxoah**™

**REF**



**SN**



*Nyxoah S.A  
Rue Edouard Belin 12,  
1435 Mont-Saint-Guibert,  
Belgium*



FCC ID: 2A6HG-NX-ASM-002325



+27°C  
+81°F

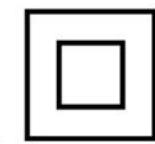
+15°C  
+59°F

80%

15%



**IP22**



(01)05404031024847  
(10)YYMMXXXX  
(11)040104  
(21)AC-LLYYXXXX

**Rx**  
only

**MD**

**CE**  
0344

GAC-000-001360 Rev XX

<p><b>XXXX: 2.0</b> Representing AC model number</p> <p><b>REF: Product PN</b></p> <p><b>SN:</b> According to PRO-0000015 Product identification and traceability procedure</p> <p><b>Date of Manufacture:</b> YYYY-MM YYYY - Year of manufacture MM - Month of manufacture</p> <p><b>2.0</b></p>	<p><b>Genio® AC XXXX</b></p> <p><b>Nyxoah</b></p> <p><b>REF</b> <input type="text"/> <b>SN</b> <input type="text"/>  <input type="text"/></p> <p><b>Nyxoah S.A</b> Rue Edouard Belin 12, 1435 Mont-Saint-Guibert, Belgium</p> <p><b>GAC-000-001304 Rev02</b></p> <p><b>75 mm</b></p> <p><b>75 mm</b></p> <p><b>CAUTION - Investigational device.</b> Limited by Federal (or United States) law to investigational use. <b>PRECAUCIÓN:</b> dispositivo para fines de investigación clínica. Limitado por la Ley Federal (o de los Estados Unidos) para el uso en investigación clínica.</p> <p><b>IP22</b></p> <p><b>2.0</b></p> <p><b>For Reference Only 2.0</b></p> <p><b>(01)05404031020139</b> <b>(10)YYMMXXXX</b> <b>(11)040104</b> <b>(21)AC-LLYYYY</b></p>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Document Revision</td> <td style="width: 25%;">ECR-ECO#</td> <td style="width: 25%;">Revision / Description</td> </tr> <tr> <td>1.0</td> <td>2020-018</td> <td>Initial release</td> </tr> <tr> <td>2.0</td> <td>CC-0000018</td> <td>Add UDI, product model number and warning in Spanish</td> </tr> </table> <p><b>CATALOG No.</b> NX-LBL-002297    <b>DRAWING No.</b> GAC-000-001304    <b>REV</b> 2.0</p> <p><b>TITLE</b> AC package label for IDE US</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">MATERIAL: See notes</td> <td style="width: 40%;">ASSEMBLY No. NA</td> </tr> <tr> <td>FINISH: See notes</td> <td></td> </tr> <tr> <td colspan="2" style="text-align: center;">DIMENSIONS ARE IN MM. GENERAL TOLERANCES UNLESS OTHERWISE SPECIFIED: <b>LINEAR DIMENSIONS</b>   <b>ANGULAR</b> 0-20   20&amp;up ±0.05   ±0.1   ±0.1° FOR UNSPECIFIED DIMENSIONS USE: MODEL AND GEOM. TOLERANCES</td> </tr> <tr> <td>DRAWN</td> <td>Galia B.</td> <td></td> <td>29-Nov-2022</td> </tr> <tr> <td>DESIGNED</td> <td>Galia B.</td> <td></td> <td>29-Nov-2022</td> </tr> <tr> <td>CHECKED</td> <td>N/A</td> <td></td> <td></td> </tr> <tr> <td>CHECKED</td> <td>Yana B.</td> <td></td> <td>30-Nov-2022</td> </tr> <tr> <td>APPROVED</td> <td>Assaf L.</td> <td></td> <td>01-Dec-2022</td> </tr> </table> <p><b>PROPRIETARY AND CONFIDENTIAL</b> THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF Nyxoah <b>Sa</b>. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF Nyxoah <b>Sa</b>. IS PROHIBITED.</p> <p><b>PROJECTION.</b> </p> <p><b>BREAK BURRS AND SHARP EDGES</b></p> <p><b>Nyxoah</b> <small>The partner for insights</small></p> <p><b>WEIGHT:</b> <b>SIZE</b> A3    <b>SCALE:</b> 1:1    <b>SHEET 1 OF 1</b></p>	Document Revision	ECR-ECO#	Revision / Description	1.0	2020-018	Initial release	2.0	CC-0000018	Add UDI, product model number and warning in Spanish	MATERIAL: See notes	ASSEMBLY No. NA	FINISH: See notes		DIMENSIONS ARE IN MM. GENERAL TOLERANCES UNLESS OTHERWISE SPECIFIED: <b>LINEAR DIMENSIONS</b> <b>ANGULAR</b> 0-20   20&up ±0.05   ±0.1   ±0.1° FOR UNSPECIFIED DIMENSIONS USE: MODEL AND GEOM. TOLERANCES		DRAWN	Galia B.		29-Nov-2022	DESIGNED	Galia B.		29-Nov-2022	CHECKED	N/A			CHECKED	Yana B.		30-Nov-2022	APPROVED	Assaf L.		01-Dec-2022
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