Ceiling hoist

Product-information/change GH3

Product-information No. 01-693 Skejby, Date 20.03.2018

Ready for order by 1. April 2018



Guldmann™

Termination of UL Certified GH3 by 1. April 2018

We have decided to terminate our UL Certification on GH3, we will continue and maintain the UL certification/listing of the transformer/power supply for GH3.

Together with the above decision we took the decision to have our GH3 tested/evaluated according to IEC 60601-1 3.1 edition by a 3rd part test institute.

This 3rd part evaluation is to confirm that we as a manufacture fulfil the requirements described in IEC 60601-1 3.1 edition and for that we have a CB Certificate.

- IEC 60601 is a series of technical standards for the safety and essential performance of medical electrical equipment.
- Compliance is mandatory but not subject for national inspection.
- The CB certificate states that the Guldmann GH3 family meets the demands of the IEC 60601-1 by test and review.
- CB certificate issued by <u>IEC and IECEE</u> to replace UL approval
- IEC and IECEE is worldwide recognized and has 53 member Countries
- (IECEE, the IEC System for Conformity Assessment Schemes for Electro-technical Equipment and Components, is a multilateral certification system based on IEC International Standards. Its Members use the principle of mutual recognition (reciprocal acceptance) of test results to obtain certification or approval at national levels around the world.)

Compliance with 60601-1 is the same whether you obtain an UL Certification or a CB certificate. The CB certificate is recognized worldwide – also in the US.

Moving forward:

We will now terminate and close all item numbers for Non-UL hoist where we have a similar item Number that previously was a UL Certified Hoist.

We will not have a UL hoist anymore and all UL logo will be removed from the hoist. The same will happen on all printed material related to the GH3 like user manuals etc.

The transformer for GH3 will continue to hold the UL Certification and UL logo will remain on the sticker/label.

We can sell all what was produced at the time when we hold the UL Certification for hoist, also after we have terminated the UL Certification.

It is important to realize that a CB Certification is still a <u>3rd. party certification</u>, meaning we still stand above the standard requirement for Medical Device Class I, where we as manufacture can sign the CE-Conformity our self, saying that we confirm and fulfil the requirements in IEC 60601-1.

When needed in Tenders you should look for a local member to point the Certification towards <u>National Certification Bodies</u>. Every country who is a CB member is obligated to accept the CB-certificate issued by an accredited institute or "National Certification Bodies". No additional approvals or testing should be needed.

The list below will show the item Numbers, marked with yellow, that will be closed in M3 as soon our inventory is empty.

Item	
552103	GH3 200 110 0000
552141	GH3 200 110 0000 Non-UL
552099	GH3 250 110 0000
552140	GH3 250 110 0000 Non-UL
552063	GH3+ 250 110 0000
552133	GH3+ 250 110 0000 Non-UL
552047	GH3+ 250 110 0010
552129	GH3+ 250 110 0010 Non-UL
552031	GH3+ 250 110 0100
552127	GH3+ 250 110 0100 Non-UL
552015	GH3+ 250 110 0110
552124	GH3+ 250 110 0110 Non-UL
552062	GH3+ 250 110 1000
552132	GH3+ 250 110 1000 Non-UL
552014	GH3+ 250 110 1110
552123	GH3+ 250 110 1110 Non-UL
552095	GH3+ 300 120 0000
552139	GH3+ 300 120 0000 Non-UL
552087	GH3+ 300 120 0010
552137	GH3+ 300 120 0010 Non-UL
552079	GH3+ 300 120 0100
552136	GH3+ 300 120 0100 Non-UL
552071	GH3+ 300 120 0110
552135	GH3+ 300 120 0110 Non-UL

	GH3+ 300 120 1000
552138	GH3+ 300 120 1000 Non-UL

552070	GH3+ 300 120 1110
552134	GH3+ 300 120 1110 Non-UL

552059 GH3+ 350 120 0000 552131 GH3+ 350 120 0000 Non-UL

552043 GH3+ 350 120 0010 552128 GH3+ 350 120 0010 Non-UL

552027 GH3+ 350 120 0100 552126 GH3+ 350 120 0100 Non-UL

552011 GH3+ 350 120 0110 552122 GH3+ 350 120 0110 Non-UL

552058 GH3+ 350 120 1000 552130 GH3+ 350 120 1000 Non-UL

552026 GH3+ 350 120 1100 552125 GH3+ 350 120 1100 Non-UL

552010 GH3+ 350 120 1110 552121 GH3+ 350 120 1110 Non-UL

552154 GH3+ 350 120 11110 WIFI 552160 GH3+ 350 120 11110 Non-UL WIFI

552114	GH3+Twin 500 220 0000
552112	GH3+Twin 500 220 0000 Non-UL