



## FUNCTIONAL SAFETY CERTIFICATE

This is to certify that the

***DB3B & DB3BM – Sounder  
DB4B & DB4BM - Loudspeaker***

manufactured by

***Eaton MEDC Ltd.***

Unit B Sutton Parkway  
Oddicroft Lane  
Sutton-in-Ashfield  
NG17 5FB

have been assessed by Sira Certification Service with reference to the  
CASS methodologies and found to meet the requirements of

**IEC 61508-2:2010  
Systematic Capability (SC2)**

as an element/subsystem suitable for use in safety related systems performing safety  
functions up to and including

**SIL 2 capable with HFT=0 (1oo1) \***

when used in accordance with the scope and conditions of this certificate.

\* This certificate does not waive the need for further functional safety verification to  
establish the achieved Safety Integrity Level (SIL) of the safety related system

Certification Decision:   
James Lynskey

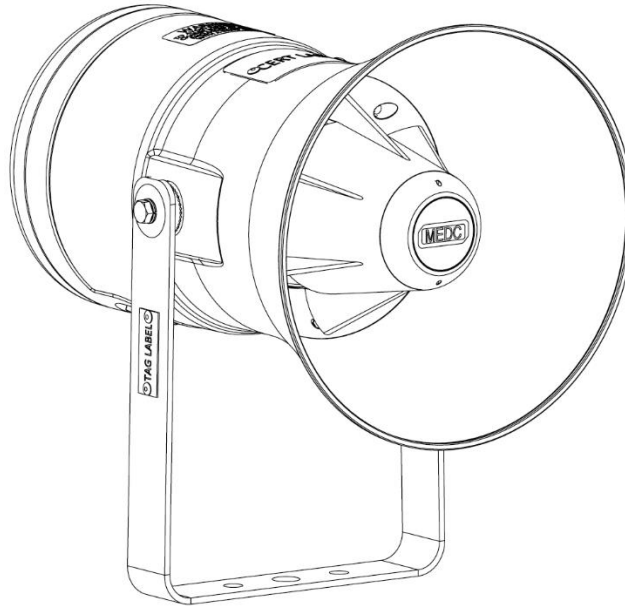
Initial Certification : 09 September 2022  
This certificate re-issued : 22 January 2024  
Renewal date : 08 September 2027

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## Product description and scope of certification

This range of horns, suitable for fire alarm or general use, is intended for use in potentially explosive gas (G) or gas and dust (GD) atmospheres. The enclosure is manufactured from a UV stable glass reinforced polyester with a rugged thermoplastic flare. Stainless steel mounting bracket, cover screws and fixings are incorporated throughout thus ensuring a corrosion free product.



**Figure 1: Typical Assembly of the DB3B(M) & DB4B(M)**

### Element Safety Function

The element safety function of the DB3B(M) is defined as follows:

- *The safety function of the Sounder is to provide a pre-determined audible warning sound when required if the correct voltage is applied to the unit. The DC version of the Sounder is designed to operate on a supply voltage between 12-48v dc.*

The element safety function of the DB4B(M) is defined as follows:

- *The safety function of the Speaker is to provide an audible warning when required.*

### Certified Data in support of use in safety functions

The assessment has been carried out with reference to the *Conformity Assessment of Safety-related Systems (CASS)* methodology using the Route 1<sub>H</sub> approach.

Based on the document submitted by Eaton MEDC Ltd., the Failure Mode and Effect Analysis (FMEA) of the DB3B(M) Sounder & DB4B(M) Loudspeaker has verified the documents as evidence of conformity to IEC 61508-2:2010 in respect of 'hardware safety integrity'. Component failure rates have been sourced against the failure modes using Item software reliability package.

The results in the tables below summarise the DB3B(M) Sounder & DB4B(M) Loudspeaker FMEA assessment and achieved safety integrity level.

**Table 1: Summary of proven in use assessment of the DB3B(M) (1oo1)**

Parameter name	Symbol	Equation / source	Results
Hardware Fault Tolerance	HFT	Architecture of the valve	0
Proof Test Interval	T	Proof test in hours	8760 (1 yr)
Mean Time To Repair	MTTR	Mean time to repair in hours	3
Type A/B	Type A	Product classification	Type B
Dangerous undiagnosed failures	$\lambda_{DU}$	From return data (Route 2H)	1.68E-08
PFD <sub>AVG</sub>	PFD <sub>AVG</sub>	$\lambda_{DU} (T / 2 + MTTR)$	7.38E-05
SIL capability (Low demand mode)			<b>SIL 2</b>

**Note:** As per Route 2H clause 7.4.4.3.1 of IEC61508-2; a hardware fault tolerance of 1 for a specified safety function for SIL 3 unless the conditions in clause 7.4.4.3.2 are met, must apply. Clause 7.4.4.3.2 indicates that the hardware fault tolerance can be reduced if the sum of all dangerous failures does not exceed 1% of the target failure measure. This requires for the PFD value to be <1.00E-05, therefore in failing to meet this requirement the device is limited to SIL 2 with HFT = 0.

**Table 2: FMEA Summary for the DB4B(M) in single mode (1oo1) and redundant mode (1oo2)**

<b>Safety Function:</b>	
<i>To provide a pre-determined audible warning sound when required if the correct voltage is applied to the unit.</i>	
<b>Summary of IEC 61508-2 Clauses 7.4.2 and 7.4.4</b>	<b>DB4B(M) (1oo1)</b>
Architectural constraints & Type of product A/B	<b>HFT = 0 Type A</b>
Safe Failure Fraction (SFF)	<b>71.5%</b>
Random hardware failures: [h <sup>-1</sup> ]	$\lambda_{DD}$ 0.00E-00 $\lambda_{DU}$ 2.88E-08
Random hardware failures: [h <sup>-1</sup> ]	$\lambda_{SD}$ 0.00E-00 $\lambda_{SU}$ 7.22E-08
Diagnostic coverage (DC)	0%
PFD @ PTI = 8760 Hrs. MTTR = 8 Hrs.	1.26E-04
Probability of Dangerous failure (High Demand - PFH) [h <sup>-1</sup> ]	2.88E-08
Hardware safety integrity compliance	Route 1 <sub>H</sub>
Systematic safety integrity compliance	Route 1 <sub>S</sub>
Systematic Capability (SC1, SC2, SC3, SC4)	<b>SC 2</b>
Hardware safety integrity achieved	<b>SIL 2</b>

**Note 1:** The failure data:

- 1) The PFD<sub>AVG</sub> figure shown is for illustration only assuming a proof test interval of 8760 hours and MTTR of 8 hours. Refer to IEC 61508-6 for guidance on PFD<sub>AVG</sub> calculations from the failure data.



- 2) The verified failure rates used in the safe failure fraction and diagnostic coverage do not include ( $\lambda$  no parts or no effect) failures in the calculation.

The failure data above is supported by the base information given in Table 3 below.

**Table 3:** Base information for the DB3B(M) & DB4B(M)

1	Product identification:	DB3B(M) & DB4B(M)
2	Functional specification:	<i>DB3B(M) - To provide a pre-determined audible warning sound when required if the correct voltage is applied to the unit. DB4B(M) - To provide a pre-determined audible warning sound when required if the correct voltage is applied to the unit.</i>
3-5	Random hardware failure rates:	Refer to table 1 and 2 of this certificate.
6	Environment limits:	Operating temperature: -20 to +60 °C.
7	Lifetime/replacement limits:	25 years
8	Proof Test requirements:	Refer to safety manual: <ul style="list-style-type: none"> <li>tm261-medc-db3b-sounder-ul</li> <li>tm262-medc-db4b-loudspeaker-ul</li> </ul>
9	Maintenance requirements:	Refer to safety manual: <ul style="list-style-type: none"> <li>tm261-medc-db3b-sounder-ul</li> <li>tm262-medc-db4b-loudspeaker-ul</li> </ul>
10	Diagnostic coverage:	Refer to table 1 and 2 of this certificate.
11	Diagnostic test interval:	Refer to safety manual: <ul style="list-style-type: none"> <li>tm261-medc-db3b-sounder-ul</li> <li>tm262-medc-db4b-loudspeaker-ul</li> </ul>
12	Repair constraints:	Refer to safety manual: <ul style="list-style-type: none"> <li>tm261-medc-db3b-sounder-ul</li> <li>tm262-medc-db4b-loudspeaker-ul</li> </ul>
13	Safe Failure Fraction:	DB3B(M) – 65.9% DB4B(M) – 71.5%
14	Hardware fault tolerance (HFT):	Refer to table 1 and 2 of this certificate.
15	Highest SIL (architecture/type A/B):	Type B – DB3B(M) Type A - DB4B(M)
16	Systematic failure constraints:	See R80122812A.
17	Evidence of similar conditions in previous use:	Not applicable.
18	Evidence supporting the application under different conditions of use:	Not applicable.
19	Evidence of period of operational use:	Not applicable.
20	Statement of restrictions on functionality:	See R80122812A.
21	Systematic capability (SC1, SC2, SC3)	SC2 - See R80122812A.
22	Systematic fault avoidance measures:	See R80122812A.
23	Systematic fault tolerance measures:	See R80122812A.
24	Validation records:	See R80122812A.

### Management of functional safety

The assessment has demonstrated that the product is supported by an appropriate functional safety management system that meets the relevant requirements of IEC 61508-1:2010 clause 6, see latest recertification (R800000491A).

### Identification of certified equipment

The certified equipment and it's safe use is defined in the manufacturer's documentation listed in Table 3 below.



**Table 4:** Certified documents

Document no.	Pages	Rev	Date	Document description
419-196A	1 of 1	1	14 Apr 2014	DB3B Schematic
399-122	1 of 1	B	14 Oct 2014	DB4B Schematic
RD419-CI-008	1 to 4	-	-	DB3B Bill of Materials - PXESA156001, PXESA156002, PXESA156003, and PXESA156004 variants.

### Conditions of Certification

The validity of the certified base data is conditional on the manufacturer complying with the following conditions:

1. The manufacturer shall analyse failure data from returned products on an on-going basis. Sira Certification Service shall be informed in the event of any indication that the actual failure rates are worse than the certified failure rates. (A process to rate the validity of field data should be used. To this end, the manufacturer should co-operate with users to operate a formal field-experience feedback programme).
2. Sira shall be notified in advance (with an impact analysis report) before any modifications to the certified equipment or the functional safety information in the user documentation is carried out. Sira may need to perform a re-assessment if modifications are judged to affect the product's functional safety certified herein.
3. On-going lifecycle activities associated with this product (e.g., modifications, corrective actions, field failure analysis) shall be subject to surveillance by Sira in accordance with 'Regulations Applicable to the Holders of Sira Certificates'.

### Conditions of Safe Use

The validity of the certified base data in any specific user application is conditional on the user complying with the following conditions:

1. The user shall comply with the requirements given in the manufacturer's user documentation in regard to all relevant functional safety aspects such as application of use, installation, operation, maintenance, proof tests, maximum ratings, environmental conditions, and repair.
2. Selection of this product for use in safety function and the installation, configuration, overall validation, maintenance and repair shall only be carried out by competent personnel, observing all the manufacturer's conditions and recommendations in the user documentation.
3. All information associated with any field failures of this product should be collected under a dependability management process (e.g., IEC 60300-3-2) and reported to the manufacturer.
4. The safety device is to have an independent power supply, it must not share the same power supply as non-safety devices that may cause a fault to the safety device.
5. A proof test interval of 1 year.

### General Conditions and Notes

1. This certificate is based upon a functional safety assessment of the product described in Sira Test & Certification Assessment Report R80122812A and any further reports referenced.
2. If the certified product or system is found not to comply, Sira Certification Service should be notified immediately at the address shown on this certificate.
3. The use of this Certificate and the Sira Certification Mark that can be applied to the product or used in publicity material are subject to the 'Regulations Applicable to the Holders of Sira Certificates' and 'Supplementary Regulations Specific to Functional Safety Certification'.



4. This document remains the property of Sira and shall be returned when requested by the issuer.
5. No part of the Functional safety related aspects stated in the instruction manual shall be changed without approval of the certification body.
6. This certificate will remain valid subject to completion of two surveillance audits within the five year certification cycle, and upon receipt of acceptable response to any findings raised during this period. This certificate can be withdrawn if the manufacturer no longer satisfies scheme requirements.

### Certificate History

Issue	Date	Report no.	Comment
00	09/09/2022	R80122812A	The release of prime certificate.
01	26/10/2022	R80122812A	Update to assessment to include different microcontroller variants. Table 4 updated.
02	22 Jan 2024	80161666 R80122812A v2.0	Updated to include Route 2H (PIU) calculations for DB3B and DB3BM only.
03	22 Jan 2024	80161666	Minor change to front page.

