

Technical file: Eyemind ApS
Document ID: 8356042
Basic UDI-DI: 574400435GazeDriver0012U

Declaration of conformity for GazeDriver

The device is in conformity with Medical Device regulation (EU) 2017 /745

| Subject | Information |
|---|--|
| Name and address of Manufacturer | Eyemind ApS Vesterbrogade 125, 1. Th 1620 Copenhagen Denmark |
| SRN Number of the Manufacturer | DK-MF-000032071 |
| Basic UDI-DI | 574400435GazeDriver0012U |
| Reference number | Model Number V001 |
| Product name/Trade name | GazeDriver |
| Intended purpose | GazeDriver is an eye-control device for wheelchairs. It is intended to be used in combination with standard powered/electrical wheelchairs to control wheelchair movement and communicate via tablet, phone, or PC. GazeDriver is intended for use in a home healthcare environment by people with a physical disability who can control their eye movement. |
| Risk class | Class I Medical Device according to Annex VIII, Chapter 3, Clause 4.1 |
| Reference to standards if applicable | No applicable product standards |
| Notified body name and number (if relevant) | Not relevant |

This EU Declaration of Conformity is issued under the sole responsibility of:

Eyemind ApS
Vesterbrogade 125, 1. Th
1620 Copenhagen
Denmark

Place, date: Copenhagen 17/5-2023

Signed on behalf of: Eyemind ApS

signature:

Name: Gitte Kim Søbørg
Position: CEO, owner of company



Vesterbrogade 125, 1. th – 1620 København V – VAT number: 37235262

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| Revision number + Date | Change | Responsible |
|---------------------------|--|-------------|
| | Please refer to Confluence page: Declaration of Conformity (DoC) GazeDriver, Document ID: 8356042 | |
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