

Certificate for Personal Protective Equipment (PPE)

This is to certify that, in accordance with the Regulation (EU) 2016/425 on personal protective equipment, MDSS GmbH agrees to perform all duties and responsibilities as the Authorised Representative for:

Key Surgical LLC 8101 Wallace Road Eden Prairie, MN 55344 USA

as stipulated and demanded by the aforementioned Regulations.

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the Personal Protective Equipments listed on the following Annex A fulfill the applicable requirements of Regulation (EU) 2016/425.

Issued: 2024-01-26 (YYYY-MM-DD)

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 745924

This certificate is subject to the following terms and conditions:

It is only valid for the device(s) listed hereafter;

It is not a proof for compliance.

The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;

As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s);

This certificate is valid for 5 years or until expiry of the EU Declaration of Conformity or Notified Body Certificate if applicable, whichever comes first.



Annex A

PPE Brand name PPE Product name & Product reference	Category according to PPE Regulation (EU) 2016/425 Annex I	Conformity assessment procedure according to PPE Regulation (EU) 2016/425 Article 19	NB No./ NB Certificate No.	NB Certificate expiry date
Face Shields	I	Annex IV (Module A)	N.A.	N.A.
4505, 4506, 4509, EN10152AF				
Safety Goggles		Annex IV (Module A)	N.A.	N.A.
09082, 09082-250, 09431, 09081, 09809, 09810, 09808, 09081-100				