

# EU Declaration of Conformity

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

declare that the new PPE described hereafter

Product Name	Model	PPE Category
Barrier Gowns	PS-110, PS-150, PS-160, PS-170, 09401, 09402, 09437, 09442, 09445, 09480	I
Face Shields	4505, 4506, 4509, 4519, 4600, 4610, 4615, 4620, 4625, EN 10152	I
Shoe Covers	PS-6502	
Beard Covers	PS-21801	I
Bouffant Caps	PS-12101, PS-12401	I
Coveralls	PS-4301, PS-4401, PS-4501, PS-4601, PS-4701, PS-4801, PS-4901	I
Safety Goggles	09082, 09431, 09081, 09809, 09810	I
Clogs	26418, 26419, 26420, 26421, 26422, 26423, 26424, 26425, 26426, 26427, 26428, 26429, 26430, 26431, 26404	I
Sleeves	PS-51801, PS-52101	I



**KEYSURGICAL**

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is in conformity with the provisions of Regulation (EU) 2016/425 and the fulfilment of the applicable essential health and safety requirements set out in Annex IV has been demonstrated.

- Harmonised standards used: EN ISO 13485:2016, ISO 14971:2007, EN ISO 14971:2012, BS EN ISO 15223-1:2016

We explicitly designate MDSS GmbH located in Schiffgraben 41, 30175 Hannover Germany to act as our sole Authorized Representative in the European Union for the above indicated products.

Issued By:

Signature:



Date: 07/30/2020

Name:

Kasey Koenig

Position:

Director, Global Quality & Regulatory