

Category II PPE 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
Heat Protective Gloves	09484, 09368	II

is in conformity with the provisions of Regulation (EU) 2016/425 and the fulfillment of the applicable essential health and safety requirements set out in Annex VI has been demonstrated and, where such is the case, with harmonized standard No. EN 407:2004 (DIN EN 407:2004-11) and EN 420:2003+A1:2009 (DIN EN 420:2010-03) where the notified body HOHENSTEIN LABORATORIES GMBH & CO. KG (NB 0555). Schloß Hohenstein 74357 Bönnigheim, Germany performed the EU type-examination (Module B) and issued EU Type Examination Certificate No. 18.1.12.1057.

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:



Steve Deline, MS RAS
Manager, Regulatory Affairs
Key Surgical LLC

Date: 2023-04-04

Place of Issue: Key Surgical LLC
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