

13 January 2022

EU CONFORMITY DECLARATION

Edgewell Personal Care solely declares basic requirements conformity in accordance with European Union Medical Device Regulation (EU) 2017/745 (EU MDR) and Article 19, Annex IV.

It is herewith self-certified that the below products are in accordance with the above mentioned EU MDR for a Class I medical device. See attached addendum.

Wilkinson Sword Hospital Disposable Razors

*Product Code No: 7000182H with one blade
7000188H with a double blade*



All products are manufactured by Edgewell Personal Care Brands, LLC in our German facility:

Wilkinson Sword GmbH
Schutzenstr. 110
D-42659 Solingen, Germany

Should you have any further enquiries, please do not hesitate to contact the undersigned.



Sandra M. Browne
Sr. Global Regulatory Manager

ANNEX IV

EU DECLARATION OF CONFORMITY

1. Name, registered trade name or registered trade mark and, if already issued, SRN as referred to in Article 31 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established; - **SRN number will be supplied upon receipt from authorities expect by March 2022.**
2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer; **We confirm that our declaration of conformity is under our sole responsibility as Wilkinson Sword GmbH - manufacturer.**
3. The Basic UDI-DI as referred to in Part C of Annex VI; **N/A**
4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3; **N/A**
5. Risk class of the device in accordance with the rules set out in Annex VIII; **CLASS 1**
6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity; **Regulations as listed above applied.**
7. References to any CS used and in relation to which conformity is declared; **N/A**
8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued; **Self Certified.**
9. Where applicable, additional information; **N/A**
10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature. **Sandra Browne, Sr. Global Regulatory Manager and Responsible Contact Person to the Authorities for Wilkinson Sword/Edgewell Products, located in European Union.**