EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: Gauke Healthcare Co.,Ltd Chengnan Industrial Park, Tuanfeng County, HuangGang, Hubei 438800, China **Prolinx GmbH European Authorized Representative:** Brehmstr.56 40239, Duesseldorf Germany We declare under our sole responsibility that the medical device: Sterile Non-woven Sponges / Balls umdns code: 13695 of class: Class Is meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. Conformity assessment procedure: Directive 93/42/EEC Annex VII in connection with Annex V DD 60145757 0001 Registration No.: 2024-05-26 Exp date: **TÜV Rheinland LGA Products GmbH** Notified Body: Tillystraße 2 90431 Nürnberg Deutschland **CE 0197** Huanggang, 20. JAN. 2021

Place, date

Name and function: Johnny Sui / General manager