

EU DECLARATION OF CONFORMITY**We,**

Medicom Healthcare BV, Parallelweg 80-A, 3931 Woudenberg, The Netherlands

hereby declare, under our sole responsibility as the manufacturer of the devices, that the following devices are in compliance with the Regulation (EU) 2017/745 .The devices have been designed and manufactured in compliance with the **GENERAL SAFETY AND PERFORMANCE REQUIREMENTS** according to the Regulation (EU) 2017/745 specified in **Annex I** , in combination with the applicable requirements of **Annex II** and **Annex III**. Furthermore we declare and assure, that the devices covered by this declaration comply with other relevant Union legislation providing for the issuance of an EU declaration of conformity, if applicable.

Product Name: Sterilisation Pouches and Sterilisation Reels (Sterile Barrier Systems)**Intended purpose:**

These single-use, preformed and sealable reels and pouches are intended to get used for the sterilization of medical devices, in healthcare facilities (medical, dental). The devices are intended to be used as a sterile barrier for the enclosed medical devices that will be terminally sterilized with a steam sterilization process or ethylene oxide gas sterilization process by a health care provider. They are intended to maintain sterility of terminally sterilized medical devices until the point of use.

Classification according to Annex VIII of the MDR 2017/45: Class I, Rule I. (No other rule is applicable)**Basic UDI-DI:** 87202499STPORO01N9

REF	Type of sterilization packaging	Dimensions
88000	Flat Self- Seal Pouches	70mm x 229mm
88005	Flat Self- Seal Pouches	89mm x 133mm
88010	Flat Self-Seal Pouches	89mm x 229mm
88015	Flat Self-Seal Pouches	57mm x 102mm
88025	Flat Self-Seal Pouches	133mm x 254mm
88030	Flat Self-Seal Pouches	191mm x 330mm
88035	Flat Self-Seal Pouches	254mm x 356mm
88040	Flat Self-Seal Pouches	305mm x 432mm
9850	Flat Reels	50mm x 200mm
9860	Flat Reels	75mm x200mm
9870	Flat Reels	100mm x 200mm
9880	Flat Reels	150mm x 200mm
9890	Flat Reels	200mm x 200mm
98100	Flat Reels	250mm x 200mm
98110	Flat Reels	300mm x 200mm

The following harmonised standards and technical specifications have been applied: EN 868-5, ISO 11607-1, ISO 11607-2, ISO 11140-1

Name: Oliver Köhn**Place of issue:** Leverkusen**Function:** Person Responsible for Regulatory Compliance**Date of issue:** 11th of May, 2021**Signature:** 