

**EU DECLARATION OF CONFORMITY****We,**

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

SRN ( Single Registration Number ) : NL-MF-000007490

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:** 87202499STPOR001N9

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:** 25<sup>th</sup> of Feb., 2022**Signature:** 