# EU DECLARATION OF CONFORMITY

**We,**

MEDICOM Healthcare BV,
Parallelweg 80-A, 3931 MT Woudenberg, The Netherlands
SRN ( Single Registration Number ) : NL-MF-000007490

Declare that the declaration of conformity is issued under our sole responsibility and relates to the following products:

**Basic UDI-DI:** 87202499STPORO01N9

| REF | Product Trade Name | Dimensions |
|---|---|---|
| 88000 | Medicom® SafeSeal® Quattro Sterilization Pouches, flat | 70mm x 229mm |
| 88005 | Medicom® SafeSeal® Quattro Sterilization Pouches, flat | 89mm x 133mm |
| 88010 | Medicom® SafeSeal® Quattro Sterilization Pouches, flat | 89mm x 229mm |
| 88015 | Medicom® SafeSeal® Quattro Sterilization Pouches, flat | 57mm x 102mm |
| 88025 | Medicom® SafeSeal® Quattro Sterilization Pouches, flat | 133mm x 254mm |
| 88030 | Medicom® SafeSeal® Quattro Sterilization Pouches, flat | 191mm x 330mm |
| 88035 | Medicom® SafeSeal® Quattro Sterilization Pouches, flat | 254mm x 356mm |
| 88040 | Medicom® SafeSeal® Quattro Sterilization Pouches, flat | 305mm x 432mm |
| 9850 | Medicom® SafeSeal® Quattro Sterilization Reels, flat | 50mm x 200mm |
| 9860 | Medicom® SafeSeal® Quattro Sterilization Reels, flat | 75mm x200mm |
| 9870 | Medicom® SafeSeal® Quattro Sterilization Reels, flat | 100mm x 200mm |
| 9880 | Medicom® SafeSeal® Quattro Sterilization Reels, flat | 150mm x 200mm |
| 9890 | Medicom® SafeSeal® Quattro Sterilization Reels, flat | 200mm x 200mm |
| 98100 | Medicom® SafeSeal® Quattro Sterilization Reels, flat | 250mm x 200mm |
| 98110 | Medicom® SafeSeal® Quattro Sterilization Reels, flat | 300mm x 200mm |

**Product group:** Sterile barrier system products

**Intended use:** 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**
The products are classified as Medical Devices according to definition of the MDR 2017/745.
They are class I products according to Annex VIII, rule 1 of the MDR 2017/745. No other rule is applicable

**The devices covered by this declaration comply with the Regulation (EU) 2017/745 on Medical Devices.**

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

**Conformity assessment procedure:**
The products are subjected to the procedures set out in Annex I, Annex II and Annex III of Regulation (EU) 2017/745.
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.

**Name:** Joachim Siegler

**Function:** General Manager

**Signature:**

**Place of issue:** Leverkusen

**Date of issue:** 15.02.2023