

# EU-Declaration of conformity

within the meaning of the Regulation (EU) 2017/745 (MDR)



We declare under our own responsibility the conformity of the following products with the Regulation (EU) 2017/745 (MDR). According to annex VIII, rule 1, this products are class I products:

**Make: OP-FIX with CLIP/HOOK (Universal tube holders), Basis-UDI-DI 426046972GE0378**

| Type designation | UDI-DI        | Type designation | UDI-DI        | Type designation | UDI-DI        |
|------------------|---------------|------------------|---------------|------------------|---------------|
| GE 03-1001 G     | 4260469720451 | GE 03-1010 G     | 4260469720635 | GE 03-1102 WB    | 4260469721069 |
| GE 03-1001 WB    | 4260469720499 | GE 03-1010 RW    | 4260469720949 | GE 03-1101 GB    | 4260469721465 |
| GE 03-1001 WR    | 4260469720475 | GE 03-1011 G     | 4260469720642 | GE 03-1101 WB    | 4260469721458 |
| GE 03-1001 Y     | 4260469720505 | GE 03-1012 G     | 4260469720659 |                  |               |
| GE 03-1001 N     | 4260469720529 | GE 03-1013 G     | 4260469720666 |                  |               |
| GE 03-1001 S     | 4260469720536 | GE 03-1014 G     | 4260469720673 |                  |               |
| GE 03-1001 H     | 4260469720543 | GE 03-1015 G     | 4260469720697 |                  |               |
| GE 03-1002 R     | 4260469720550 | GE 03-1016 G     | 4260469720703 |                  |               |
| GE 03-1002 WB    | 4260469721441 | GE 03-1017 G     | 4260469720710 |                  |               |
| GE 03-1004 R     | 4260469720567 | GE 03-1022 G     | 4260469721267 |                  |               |
| GE 03-1005 G     | 4260469720574 | GE 03-1027 G     | 4260469720727 |                  |               |
| GE 03-1006 R     | 4260469720581 | GE 03-1029 WR    | 4260469721151 |                  |               |
| GE 03-1006 WR    | 4260469720598 | GE 03-1101 G     | 4260469721342 |                  |               |
| GE 03-1009 G     | 4260469720628 | GE 03-1102 G     | 4260469721229 |                  |               |

We confirm that above-mentioned products have been developed, designed and manufactured in accordance with annex I of Regulation (EU) 2017/745 (MDR).

Applied harmonized standards, national standards or other normative documents:

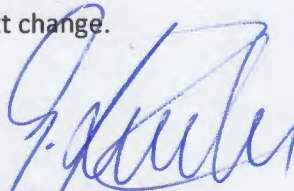
|                                |                             |                  |
|--------------------------------|-----------------------------|------------------|
| Verordnung (EU) 2017/745 (MDR) | Medizinproduktegesetz (MPG) | EN ISO 15223-1   |
| EN 1041:2013-12                | EN ISO 10993-1:2010-04      | EN 15986:2011-05 |
| EN ISO 10993-10:2014-10        | EN ISO 14971:2013-04        |                  |

The necessary technical documentation according to annex II and III of Regulation (EU) 2017/745 (MDR) is completely available.

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**SRN:** DE-MF-000006156

This document is valid until May 31, 2023 or until the next change.



Gerd Riester, owner

Jungingen, 01.06.2021