



EU Declaration of Conformity

Legal Manufacturer

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| - Name | ABENA A/S | www.abena.com |
| - Address | Egelund 35 | Phone: +45 7431 1818 |
| - Phone / fax / email / webpage | DK-6200 Aabenraa Denmark | Fax: +45 7462 9737 Mail: info@abena.com |
| - Single Registration Number (SRN) | DK-MF-000002482 | |

Medical Device(s)

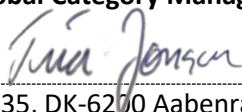
| | |
|---|---|
| - Basic UDI-DI | Please see appendix I |
| - Product/trade name(s) and product code(s) (REF)/and or catalogue number | Please see appendix I |
| - Other ref. allowing identification (e.g. UDI-DI) | Please see appendix I |
| - Intended Purpose | Please see appendix I |
| - Risk classification | Class I according to rule no. 1 in MDR annex VIII |

Other information (if applicable)

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| - Common Specifications used for compliance | ISO 13485:2016 |
| - Notified Body name and identification no. and description of the conformity assessment procedure performed | N/A |
| - Additional information | N/A |
| - Standards used to assure compliance | Please see appendix II |

The above mentioned manufacturer hereby declares that the below mentioned medical device(s) are compliant with the EU Regulation 2017/745 for Medical Devices and the EU legislations mentioned under "additional information".

This Declaration of Conformity is issued under the sole responsibility of the above mentioned manufacturer.

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| Name and Function: Tina Jönson, Global Category Manager | Place and date of issue Aabenraa, DK, 31.08.2022 |
| Signature  | |
| Abena, Egelund 35, DK-6200 Aabenraa | |

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| Template Responsible: JOHO | Created: JOHO | Approved: ULDA |
| File: DoC External MDR - Scrub suit Excellent | Revision/Version: 1.2 | Date: 16-06-2021 |
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Appendix I, List of products

| Product Name | Item no. | Basic UDI-DI | Intended Purpose |
|---------------------------------|------------|---------------------------|--|
| Scrub suit, shirt, S, Blue | 210460 | 57035380ScSuD-00I-06001AB | Comfortable shirt without cuffs for use by health care staff and patients to avoid cross contamination. Liquid repellent material, with V-neck and 3 pockets. Packaged individually. |
| Scrub suit, shirt, M, Blue | 210462 | | |
| Scrub suit, shirt, L, Blue | 210464 | | |
| Scrub suit, shirt, XL, Blue | 210466 | | |
| Scrub suit, shirt, XXL, Blue | 210468 | | |
| Scrub suit, shirt, S, Green | 210580 | | |
| Scrub suit, shirt, M, Green | 210582 | | |
| Scrub suit, shirt, L, Green | 210584 | | |
| Scrub suit, shirt, XL, Green | 210586 | | |
| Scrub suit, shirt, XXL, Green | 210588 | | |
| Scrub suit, shirt, 4XL, Green | 1000001901 | | Comfortable pants without cuffs for use by health care staff and patients to avoid cross contamination. Liquid repellent material, with waist ties. Packaged individually. |
| Scrub suit, pants, S, Blue | 210461 | | |
| Scrub suit, pants, M, Blue | 210463 | | |
| Scrub suit, pants, L, Blue | 210465 | | |
| Scrub suit, pants, XL, Blue | 210467 | | |
| Scrub suit, pants, XXL, Blue | 210469 | | |
| Scrub suit, pants, S, Green | 210581 | | |
| Scrub suit, pants, M, Green | 210583 | | |
| Scrub suit, pants, L, Green | 210585 | | |
| Scrub suit, pants, XL, Green | 210587 | | |
| Scrub suit, pants, XXL, Green | 210589 | | |
| Scrub suit, pants, 4XL, Green | 1000001902 | | Comfortable scrub suit set of shirt and pants without cuffs for use by staff and patients to avoid cross contamination. Liquid-repellent material, scrub suit shirt with a V-neck and 1 pocket, and pants with elastic waist. Packaged as a set. |
| Scrub suit, set, S, Dark blue | 210411 | | |
| Scrub suit, set, M, Dark blue | 210412 | | |
| Scrub suit, set, L, Dark blue | 210413 | | |
| Scrub suit, set, XL, Dark blue | 210414 | | |
| Scrub suit, set, XXL, Dark blue | 210415 | | |
| Scrub suit, set, 3XL, Dark blue | 210416 | | Comfortable scrub suit set of shirt and pants without cuffs for use by staff and patients to avoid cross contamination. Liquid-repellent material, scrubs suit shirt with a V-neck and 3 pockets, and pants |
| Scrub suit, set, S, Blue | 210421 | | |
| Scrub suit, set, M, Blue | 210422 | | |
| Scrub suit, set, L, Blue | 210423 | | |
| Scrub suit, set, XL, Blue | 210424 | | |
| Scrub suit, set, XXL, Blue | 210425 | | |
| Scrub suit, set, 3XL, Blue | 1000001220 | | |
| Scrub suit, set, S, Purple | 210481 | | |
| Scrub suit, set, M, Purple | 210482 | | |
| Scrub suit, set, L, Purple | 210483 | | |

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| Scrub suit, set, XL, Purple | 210484 | | with a drawstring waist. Packaged as a set. |
| Scrub suit, set, XXL, Purple | 210485 | | |
| Scrub suit, set, S, Green | 210491 | | |
| Scrub suit, set, M, Green | 210492 | | |
| Scrub suit, set, L, Green | 210493 | | |
| Scrub suit, set, XL, Green | 210494 | | |
| Scrub suit, set, XXL, Green | 210495 | | |

Appendix II, List of applicable standards used

| Product Name | Standards used |
|-----------------------------------|--------------------|
| All products listed in Appendix 1 | ENISO 14971:2019 |
| | ISO10993-1:2018 |
| | ISO10993-5:2009 |
| | ISO10993-10:2013 |
| | EN 20417:2021 |
| | ENISO 15223-1:2016 |
| | EN 13795-1:2019 |

expand list accordingly

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