

**HTL- Strefa S.A**  
ul. Adamówek 7  
95-035 Ozorków  
POLAND

**DECLARATION OF CONFORMITY**  
**medical devices rev. 53**

We hereby declare that the distributed CE marked products, specified in the annexed product list, are covered by the "CE Marking of Conformity Certificate", reference number: 84587CE01 issued for first time on 15<sup>th</sup> March 1999 and delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and conform to the required technical documentation, in accordance with Annex II of the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices and revision of directive 2007/47/EC.

In addition, we ensure and declare that distributed CE market products, as mentioned and falling within Class IIa, meet the provisions of the EU-Directive which apply to them.

This declaration is supported by the Quality System developed base on the harmonized standards:  
- EN ISO 13485:2016, Certificate no. 995651 issued first time 2004-08-25 delivered by DEKRA Certification B.V  
- ISO 13485:2016 (MDSAP), Certificate no. 2194749 issued first time 2019-01-28 delivered by DEKRA Certification B.V

This declaration of Conformity covers sterile, single use lancets, personal lancets, pen needles, lancing devices and is valid for all products concerned bearing the CE marking and manufactured at the following sites:

- Site 1: Ozorków, ul. Adamówek 7, 95-035 Poland,
- Site 2: Łęczyca, ul. Lotnicza 21h, 99-100, Poland

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### PRODUCT LIST rev. 53

Sterile, single use lancets, pen needles; non-sterile, multiple use lancing devices

This product list belongs to the Declaration of Conformity identified by document no HTL ZJ/161/2010 and specifies the CE marked products concerned that HTL-Strefa S.A. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices and revision of directive 2007/47/EC. The following list identifies the products by name and type and by serial number.

| <i>Product type according CE mark certificate /</i> | <i>Commercial Name</i>   | <i>Dimension of the needle</i>                  | <i>GMDN code</i> | <i>First lot no with CE mark:</i>   |
|---|--|---|------------------|-------------------------------------|
| <b>Safety lancet type 420</b>                       | Haemolance Plus<br>Safe-T-Lance Plus<br>McKesson Safety Lancets<br>PUSH BUTTON                         | 18G<br>21G<br>25G<br>28G<br>1.5 mm blade        | 61579            | M22A313A6<br>W43F928A8              |
| <b>Safety lancet type 430</b>                       | Prolance<br><br>Single-Let   | 18G / 21G / 25G<br>/ 28G<br>1,5 mm blade<br>28G | 61579            | P37K937G5                           |
| <b>Safety lancet type 450</b>                       | ergo@Lance   | 21G<br>25G<br>30G                               | 61579            | U50A445A9                           |
| <b>Safety lancet type 520</b>                       | Assure Lance<br>MediSafe Solo<br>MenaLancet Pro<br>Securlancets unik<br>diamet® mySafety<br>MedicoFine | 23G<br>23G/28G/29G<br>23G/29G<br>23G/29G<br>29G | 61579            | P21M114N3<br>P21N614N4<br>S14V714L1 |
| <b>Safety lancet type 532</b>                       | myLance  | 23G / 28G                                       | 61579            |                                     |
| <b>Safety lancet type 545-549</b>                   | Medlance   | 21G / 23G / 28G<br>1,5 mm blade                 | 61579            | B2D33C7<br>X30B13D5                 |
| <b>Safety lancet type 553-556</b>                   | Medlance Plus:<br>(Special, Extra, Lite,<br>Universal, SuperLite)                                      | 21G / 25G / 30G<br>0,8 mm blade                 | 61579            | J8C82A6                             |
|   | GlucoSmart   | 21G / 30G                                       | 61579            |                                     |
|   | Safe Digitest  | 21G / 25G / 30G                                 | 61579            | Z50B318C1                           |

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| <b>Product type according CE mark certificate /</b> | <b>Commercial Name</b>   | <b>Dimension of the needle</b>  | <b>GMDN code</b> | <b>First lot no with CE mark:</b> |
|---|--|---|------------------|-----------------------------------|
|   |  |   |                  |                                   |
| <b>Safety lancet type 610</b>                       | Acti-Lance   | 17G / 23G / 28G   | 61579            | P25L24K2                          |
|   | Safe Digitest PLUS   | 23G / 28G   | 61579            | Z11E443F7                         |
| <b>Personal lancet type 560</b>                     | Droplet<br>Penlancet<br>Soft Fine Colour<br>MenaLancet<br>Microdot | 28G/30G/33G   | 61579            | E6B6<br><br>P15B6                 |
|   | MyStar SylkFeel<br>Glucoject Lancets PLUS<br>GlucoSmart fine       | 28G/33G<br>33G<br>30G   |                  | T12A4<br>T53A7                    |
| <b>Lancing device type 700</b>                      | Droplet<br>MyStar SylkFeel<br>Glucoject Dual PLUS                  | n/a   | 37243            | 1505A02<br>1711A03                |
| <b>Pen Needles type 810</b>                         | Droplet / Haemofine /<br>Accu-Fine                                 | 32G x 4 mm<br>32G x 5 mm<br>32G x 6 mm<br>32G x 8 mm<br>31G x 5 mm<br>31G x 6 mm<br>31G x 8 mm<br>29G x 10 mm<br>29G x 12 mm<br>30G x 8mm<br>33G x 4mm<br>34G x 3,5mm | 44127            | P39G4<br>P39J2                    |
|   | Glucoject Pen Needles  | 32G x 4 mm<br>32G x 6 mm<br>32G x 8 mm<br>31G x 5 mm<br>31G x 6 mm<br>31G x 8 mm<br>29G x 10 mm<br>29G x 12 mm  | 44127            | T53A6<br>W46ZJ5<br>W46ZJ1         |
|   | microdot droplet   | 32G x 4mm<br>31G x 6mm<br>31G x 8mm   | 44127            | X46ZK4                            |
|   | Standard NanoFine pen<br>needles                                   | 32G x 4 mm<br>32G x 5 mm<br>32G x 6 mm<br>32G x 8 mm<br>31G x 5 mm<br>31G x 6 mm  | 44127            |                                   |
|   | diamet   | 31G x 6 mm  | 44127            |                                   |

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| <i>Product type according CE mark certificate /</i> | <i>Commercial Name</i>              | <i>Dimension of the needle</i>           | <i>GMDN code</i> | <i>First lot no with CE mark:</i> |
|---|-------------------------------------|--|------------------|-----------------------------------|
|   |                                     | 31G x 8 mm<br>29G x 10 mm<br>29G x 12 mm |                  |                                   |
|   | AviFine                             | 32G x 4 mm<br>32G x 5 mm<br>32G x 8 mm   | 44127            |                                   |
| <b>Safety Pen Needles type 820</b>                  | DropSafe<br>diamet® mySafety        | 31G x 5 mm<br>31G x 6 mm<br>31G x 8 mm   | 44127            | V55G9<br>W55A1                    |
|   | DIAVUE Prudential                   |  |                  | Y55J1                             |
|   | Safe Block                          |  |                  | Z55K7                             |
|   | MedicoFINE                          |  |                  | Z55Y6                             |
|   | McKesson Sterile Safety Pen Needles | 31G x 6 mm                               | 44127            |                                   |

Regulatory Affairs Manager

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**REVISION HISTORY**

| No. | Rev. no. | Page | Change description  | Introduced by         | Date       | Effective date |
|-----|----------|------|---|-----------------------|------------|----------------|
| 1.  | 33       | All  | Safe-T-Lance (Type 420) was added to Declaration of Conformity.<br>Gages and blades added.  | J. Żemigala           | 2017-03-24 | 2017-03-24     |
| 2.  | 34       | All  | Medlance 23G (Type 545-549) was added to Declaration of Conformity (refer to CC 79/2017 and CC – 361/2016)  | P. Potyrała           | 2017-03-31 | 2017-04-06     |
| 3.  | 35       | All  | Brand Single-Let 28G added to the Declaration of Conformity   | M. Szwolgin           | 2017-09-14 | 2017-09-14     |
| 4.  | 36       | All  | Change in version Glucoject Dual PLUS (lancing device type 700) – lot number was added to Declaration of Conformity (CC – 312/2017)   | J. Żemigala           | 2017-11-24 | 2017-02-02     |
|     |          |      | Brand microdot droplet was added for type 810 (CC 350/2017)   | B. Jarosik            | 2018-01-12 |                |
| 5.  | 37       | All  | Brand Standard NanoFine pen needles added to the Declaration of Conformity (CC 363/2017)  | K.Nożewska            | 2018-01-12 | 2018-03-01     |
| 6.  | 38       | 4    | - Phrase <i>Sterile, single use lancet, pen needles, lancing device</i> changed to <i>Sterile, single use lancets, pen needles; non-sterile, multiple use lancing devices</i>   | I.Banaś<br>J.Żemigala | 2018-05-29 | 2018-06-19     |
|     |          |      | - removed: Site 3: HTL-Strefa, Inc. 3005 Chastain Meadows Pkwy Marietta GA 30066 USA – distribution center (ECN-147/2017)<br><br>- Brand DIAVUE Prudential added to type 820 (CC 65/2018)   |                       |            |                |
| 7.  | 39       | 2-3  | - Change of GMDN Code for blood lancets (safety lancets and personal lancets) from: 37466 to 61579 (CC 9/2018)  | J.Żemigala            | 2018-06-20 | 2018-08-06     |
| 8.  | 40       | 3-4  | Brand GlucoSmart was added for type 553-556 (CC-351/2018)   | J.Żemigala            | 2018-10-15 | 2018-10-15     |
| 9.  | 41       | 2    | Typo error related to gage of Safety lancet type 430 has been corrected (23G into 21G)  | J.Żemigala            | 2018-12-06 | 2018-12-06     |
| 10. | 42       | All  | EN ISO 13485:2012 updated into EN ISO 13485:2016 based on new Certificate effective from 2019-01-28.<br>ISO 13485:2016 added as per MDSAP Certificate.<br>New brand myLance implemented and BD Sentry removed within safety lancet type 532 (CC 384/2018) | J.Żemigala            | 2019-01-30 | 2019-01-30     |
|     |          |      | New brands have been added:<br>- Safe Digitest for type 553-556 (CC-458/2018)<br>- Safe Digitest PLUS for type 610 (CC-502/2018)<br>- Safe Block for type 820 (CC-457/2018)   |                       |            |                |
| 11. | 43       | 2    | Safety lancet type 410 Haemolance Profile (CC – 163/2019) removed.  | J.Żemigala            | 2019-05-22 | 2019-08-22     |

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|     |     |     |  |               |            |            |
|-----|-----|-----|--|---------------|------------|------------|
| 12. | 44  | 2   | New brand diamet® mySafety for type 520 added (CC 137/2019)  | J.Żemigala    | 2019-09-06 | 2019-09-24 |
| 13. | 45  | 4   | New brand name MedicoFINE included in type 820 (CC 271/2019)   | I. Banaś      | 2019-09-30 | 2019-10-31 |
| 14. | 46  | 3-4 | GlucoSmart fine included in type 560 (CC 228/2018).<br>Assencia Microlet, Microlet removed from type 560.<br>Diamet included in type 810 (base on CC 177/2019) | J.Żemigala    | 2019-11-22 | 2019-11-22 |
| 15. | 47  | 3   | Brand name New Line has been removed from type 610, as it is not existing on the market and as well as in Product Specifications                               | J.Żemigala    | 2020-04-27 | 2020-04-27 |
| 16. | 48  | 2   | New version/gage 28G within Medlance safety lancet type 545-549 has been added   | J.Żemigala    | 2020-06-17 | 2020-06-17 |
| 17. | 49  | 3   | New brand: Accu-Fine within type 810 has been added  | J.Żemigala    | 2020-06-18 | 2020-06-18 |
| 18. |     |     | New gages 30G, 33G, 34G within type 810 has been added   |               | 2020-06-18 | 2020-10-05 |
| 19. | 50  | 2   | Brand MedicoFine type 520 added based on CC - 296/2020   | I. Banaś      | 2021-01-21 | 2021-01-21 |
| 20. | 51  | 4   | New version of safety pen needle added – 31Gx5mm   | I. Banaś      | 2021-04-01 | 2021-04-28 |
| 21. | 52  | 2,4 | Brands added - McKesson Safety Lancets PUSH BUTTON (type 420), McKesson Sterile Safety Pen Needles (type 820); CC 238/2020                                     | I. Banaś      | 2021-05-05 | 2021-05-17 |
| 22. | 53. | 3   | New brand: AviFine within type 810 has been added (CC-109/2022)  | Sz.Skurzyński | 2022-05-27 | 2022-06-24 |