



## **DECLARATION OF CONFORMITY**

### **Medical Devices - Respiratory Face Masks and Accessories**

We hereby declare the distributed CE marked product specified in the annexed product list are covered by the "CE Marking of Conformity Certificate", reference number CE 649013, issued on June 14, 2016 and delivered by BSI, Notified Body Identification Number 2797, and conform to the required technical documentation, in accordance with Annex VII of the "EC- Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices, including all subsequent amendments.

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

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex V of the EC-Directive. The conformity of the production quality assurance set out in the Annex V, is described in the said CE Marking of Conformity Certificate, issued and delivered by BSI.

This declaration is supported by the Quality System certification based on the harmonized standards ISO 13485; 2016, Quality System Certificate with reference number FM 645459, issued on January 19, 2016 and delivered by BSI.

We declare the EC Representative for the product specified in the product list is QNET BV, Kantstraat 19, NL-5076 NP Haaren, The Netherlands. SRN: NL-AR-000002695

This Declaration of Conformity covers the products as specified in the list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

2055 Executive Drive  
Indianapolis, IN 46241 USA

Date: December 19, 2022

Tamara Lefevers, Sr. QA/RA Manager

Annex: Product List (Rev. S)

**Medical Devices - Respiratory Face Masks and Accessories****Product List – Rev S**

| <u>Product Number</u>         | <u>Description</u>                                     | <u>1st CE Marked Lot</u> | <u>Last CE Lot</u> | <u>Pkg label</u> | <u>UDI-DI</u>  | <u>Box label</u> | <u>UDI-DI</u>  |
|-------------------------------|--------------------------------------------------------|--------------------------|--------------------|------------------|----------------|------------------|----------------|
| <b>BiTrac Full Face Masks</b> |                                                        |                          |                    |                  |                |                  |                |
| 313-9001W                     | Small Twin Lip (PD) Mask with AA Elbow/with Headgear   | 3139001080123            |                    | 3589             | 00841470106362 | 3590             | 10841470106369 |
| 313-9002W                     | Medium Twin Lip (PD) Mask with AA Elbow/with Headgear  | 3139002080123            |                    | 3591             | 00841470106379 | 3592             | 10841470106376 |
| 313-9003W                     | Large Twin Lip (PD) Mask with AA Elbow/with Headgear   | 3139003080123            |                    | 3587             | 00841470106386 | 3588             | 10841470106383 |
| 313-9004W                     | X Large Twin Lip (PD) Mask with AA Elbow/with Headgear | 3139004080123            |                    | 3124             | 00841470106393 | 3125             | 10841470106390 |
| 313-9005                      | Small Twin Lip (PD) Mask with AA Elbow/No Headgear     | 3139005090819            |                    | 7771             | 00841470107123 | 7772             | 10841470107120 |
| 313-9006                      | Medium Twin Lip (PD) Mask with AA Elbow/No Headgear    | 3139006080806            |                    | 7773             | 00841470107147 | 7774             | 10841470107144 |
| 313-9007                      | Large Twin Lip (PD) Mask with AA Elbow/No Headgear     | 3139007080806            |                    | 7775             | 00841470107154 | 7776             | 10841470107151 |
| 313-9008                      | X Large Twin Lip (PD) Mask with AA Elbow/No Headgear   | 3139008080930            |                    | 7777             | 00841470107161 | 7778             | 10841470107168 |
| 313-9009W                     | Small Twin Lip (PD) Mask with SE Elbow/with Headgear   | 3139009080123            |                    | 3575             | 00841470107017 | 3576             | 10841470107014 |
| 313-9010W                     | Medium Twin Lip (PD) Mask with SE Elbow/with Headgear  | 3139010080123            |                    | 3577             | 00841470106416 | 3578             | 10841470106413 |
| 313-9011W                     | Large Twin Lip (PD) Mask with SE Elbow /with Headgear  | 3139011080123            |                    | 3579             | 00841470106423 | 3580             | 10841470106420 |
| 313-9012W                     | X Large Twin Lip (PD) Mask with SE Elbow/with Headgear | 3139012080123            |                    | 3593             | 00841470106430 | 3594             | 10841470106437 |

|           |                                                 |                |  |      |                |      |                |
|-----------|-------------------------------------------------|----------------|--|------|----------------|------|----------------|
| 313-9035W | Extra Small RM Mask with AA Elbow/with Headgear | 3139035W130610 |  | 3888 | 00841470106782 | 3889 | 10841470106789 |
| 313-9036W | Small RM Mask with AA Elbow/with Headgear       | 3139036121121  |  | 3890 | 00841470106799 | 3891 | 10841470106796 |
| 313-9037W | Medium RM Mask with AA Elbow/with Headgear      | 3139037120710  |  | 3748 | 00841470106805 | 3747 | 10841470106802 |
| 313-9038W | Large RM Mask with AA Elbow/with Headgear       | 3139038120710  |  | 2329 | 00841470106812 | 2330 | 10841470106819 |
| 313-9039W | Extra Large RM Mask with AA Elbow/with Headgear | 3139039120710  |  | 3775 | 00841470106829 | 3776 | 10841470106826 |
| 313-9031W | Extra Small RM Mask with SE Elbow/with Headgear | 3139031W121106 |  | 3767 | 00841470106744 | 3768 | 10841470106741 |
| 313-9032W | Small RM Mask with SE Elbow/with Headgear       | 3139032W121101 |  | 3765 | 00841470106751 | 3766 | 10841470106758 |
| 313-9033W | Medium RM Mask with SE Elbow/with Headgear      | 3139033W121101 |  | 3763 | 00841470106768 | 3764 | 10841470106765 |
| 313-9034W | Large RM Mask with SE Elbow/with Headgear       | 3139034W121101 |  | 3761 | 00841470106775 | 3762 | 10841470106772 |
| 313-9046W | Small RP Mask with AA Elbow / with Headgear     | 3139046120730  |  | 3797 | 00841470106522 | 3798 | 10841470106529 |
| 313-9047W | Medium RP Mask with AA Elbow/with Headgear      | 3139047120618  |  | 3750 | 00841470106546 | 3749 | 10841470106543 |
| 313-9048W | Large RP Mask with AA Elbow/with Headgear       | 3139048120622  |  | 3795 | 00841470106553 | 3796 | 10841470106550 |
| 313-9042W | Small RP Mask with SE Elbow/with Headgear       | 3139042W121101 |  | 3773 | 00841470106492 | 3774 | 10841470106499 |
| 313-9043W | Medium RP Mask with SE Elbow/with Headgear      | 3139043W121031 |  | 3771 | 00841470106508 | 3772 | 10841470106505 |
| 313-9044W | Large RP Mask with SE Elbow/with Headgear       | 3139044W121101 |  | 3769 | 00841470106515 | 3770 | 10841470106512 |
| 313-9066W | Small FP Mask with AA Elbow/with Headgear       | 3139066W130320 |  | 2124 | 00841470106683 | 2125 | 10841470106680 |
| 313-9067W | Medium FP Mask with AA Elbow/with Headgear      | 3139067120321  |  | 3746 | 00841470106690 | 3745 | 10841470106697 |

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|-----------|---------------------------------------------------|----------------|--|------|----------------|------|----------------|
|           |                                                   |                |  |      |                |      |                |
| 313-9068W | Large FP Mask with AA Elbow/with Headgear         | 3139068120208  |  | 2126 | 00841470106706 | 2127 | 10841470106703 |
| 313-9062W | Small FP Mask with SE Elbow/with Headgear         | 3139062W121101 |  | 3759 | 00841470106652 | 3760 | 10841470106659 |
| 313-9063W | Medium FP Mask with SE Elbow/with Headgear        | 3139063120509  |  | 3757 | 00841470106669 | 3758 | 10841470106666 |
| 313-9064W | Large FP Mask with SE Elbow/with Headgear         | 3139064120710  |  | 3755 | 00841470106676 | 3756 | 10841470106673 |
| 313-9504  | X Large PD Mask with (IEC) AA Elbow/with Headgear | 3139504140617  |  | 2331 | 00841470104436 | 2332 | 10841470104433 |
| 313-9503  | Large PD Mask with (IEC) AA Elbow/with Headgear   | 3139503140429  |  | 3841 | 00841470104429 | 3842 | 10841470104426 |
| 313-9502  | Medium PD Mask with (IEC) AA Elbow/with Headgear  | 3139502140429  |  | 3843 | 00841470104412 | 3844 | 10841470104419 |
| 313-9501  | Small PD Mask with (IEC) AA Elbow/with Headgear   | 3139501140617  |  | 2313 | 00841470104856 | 2314 | 10841470104853 |
| 313-9563  | Large FP Mask with (IEC) SE Elbow / with Headgear | 3139563140609  |  | 3845 | 00841470104672 | 3846 | 10841470104679 |
| 313-9562  | Medium FP Mask with (IEC) AA Elbow/with Headgear  | 3139562140505  |  | 3847 | 00841470104665 | 3848 | 10841470104662 |
| 313-9561  | Small FP Mask with (IEC) AA Elbow/with Headgear   | 3139561140616  |  | 2333 | 00841470104658 | 2334 | 10841470104655 |
| 313-9533  | Large RM Mask with (IEC) AA Elbow/with Headgear   | 3139533140505  |  | 3849 | 00841470104542 | 3850 | 10841470104549 |
| 313-9532  | Medium RM Mask with (IEC) AA Elbow/with Headgear  | 3139532140505  |  | 3851 | 00841470104535 | 3852 | 10841470104532 |
| 313-9531  | Small RM Mask with (IEC) AA Elbow/with Headgear   | 3139531140623  |  | 2335 | 00841470104528 | 2336 | 10841470104525 |
| 313-9530  | X Small RM Mask with (IEC) AA Elbow/with Headgear | 3139530140729  |  | 2337 | 00841470104511 | 2338 | 10841470104518 |
| 313-9543  | Large RP Mask with (IEC) AA Elbow/with Headgear   | 3139543140505  |  | 3853 | 00841470104917 | 3854 | 10841470104914 |

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|----------|---------------------------------------------------------|---------------|--|------|----------------|------|----------------|
| 313-9542 | Medium RP Mask with (IEC) AA Elbow/with Headgear        | 3139542140505 |  | 3855 | 00841470104863 | 3856 | 10841470104860 |
| 313-9541 | Small RP Mask with (IEC) AA Elbow/with Headgear         | 3139541140505 |  | 2339 | 00841470104832 | 2340 | 10841470104839 |
| 313-9514 | X Large PD Mask with (IEC) AA Leak Elbow /with Headgear | 3139514141104 |  | 3910 | 00841470104504 | 3911 | 10841470104501 |
| 313-9513 | Large PD Mask with (IEC) AA Leak Elbow /with Headgear   | 3139513140514 |  | 3908 | 00841470104498 | 3909 | 10841470104495 |
| 313-9512 | Med PD Mask with (IEC) AA Leak Elbow /with Headgear     | 3139512140724 |  | 3906 | 00841470104481 | 3907 | 10841470104488 |
| 313-9511 | Small PD Mask with (IEC) AA Leak Elbow /with Headgear   | 3139511150318 |  | 3904 | 00841470104474 | 3905 | 10841470104471 |
| 313-9515 | Small PD Mask with (IEC) AA Neb Elbow /with Headgear    | 220608        |  | 2870 | 00841470104924 | 2871 | 10841470104921 |
| 313-9516 | Medium PD Mask with (IEC) AA Neb Elbow /with Headgear   | 220608        |  | 2872 | 00841470103361 | 2873 | 10841470103368 |
| 313-9517 | Large PD Mask with (IEC) AA Neb Elbow /with Headgear    | 220608        |  | 2874 | 008414703378   | 2875 | 10841470103375 |
| 313-9518 | X Large PD Mask with (IEC) AA Neb Elbow /with Headgear  | 200925        |  | 2876 | 00841470103385 | 2877 | 10841470103382 |
| 313-9578 | Large FP Mask with (IEC) AA Elbow /with Headgear        | 3139578140801 |  | 2564 | 00841470104955 | 2565 | 10841470104952 |
| 313-9577 | Medium FP Mask with (IEC) AA Leak Elbow/with Headgear   | 3139577140801 |  | 2562 | 00841470104979 | 2563 | 10841470104976 |
| 313-9576 | Small FP Mask with (IEC) AA Leak Elbow /with Headgear   | 3139576140801 |  | 2632 | 00841470104986 | 2633 | 10841470104983 |
| 313-9583 | Large RM Mask with (IEC) AA Leak Elbow /with Headgear   | 3139583140919 |  | 2574 | 00841470104733 | 2575 | 10841470104730 |
| 313-9582 | Med. RM Mask with (IEC) AA Leak Elbow/with Headgear     | 3139582140919 |  | 2572 | 00841470104726 | 2573 | 10841470104723 |

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|----------|-------------------------------------------------------------|---------------|--|------|----------------|------|----------------|
| 313-9581 | Small RM Mask with (IEC)<br>AA Leak Elbow /with<br>Headgear | 3139581170330 |  | 2511 | 00841470108304 | 2512 | 10841470108301 |
| 313-9580 | X Sm RM Mask with (IEC)<br>AA Leak Elbow /with<br>Headgear  | 3139581170330 |  | 2507 | 00841470108298 | 2508 | 10841470108295 |
| 313-9573 | Large RP Mask with (IEC)<br>AA Leak Elbow /with<br>Headgear | 3139573170801 |  | 2527 | 00841470109295 | 2528 | 10841470109292 |
| 313-9572 | Med RP Mask with (IEC)<br>AA Leak Elbow /with<br>Headgear   | 3139572160308 |  | 2158 | 00841470105020 | 2159 | 10841470105027 |
| 313-9571 | Small RP Mask with (IEC)<br>AA Leak Elbow /with<br>Headgear | 3139571170330 |  | 2725 | 00841470104719 | 2726 | 10841470104716 |
| 313-9509 | X Large PD Mask with (IEC)<br>SE Elbow/with Headgear        | 3139509140617 |  | 2341 | 00841470104900 | 2342 | 10841470104907 |
| 313-9508 | Large PD Mask with (IEC)<br>SE Elbow / with Headgear        | 3139508140510 |  | 3857 | 00841470104467 | 3858 | 10841470104464 |
| 313-9507 | Medium PD Mask with<br>(IEC) SE Elbow/with<br>Headgear      | 3139507140510 |  | 3859 | 00841470104450 | 3860 | 10841470104457 |
| 313-9506 | Small PD Mask with (IEC)<br>SE Elbow/with Headgear          | 3139506140617 |  | 2343 | 00841470104443 | 2344 | 10841470104440 |
| 313-9568 | Large FP Mask with (IEC)<br>SE Elbow/with Headgear          | 3139568140616 |  | 2345 | 00841470104702 | 2346 | 10841470104709 |
| 313-9567 | Medium FP Mask with<br>(IEC) SE Elbow/with<br>Headgear      | 3139567140616 |  | 2347 | 00841470104849 | 2348 | 10841470104846 |
| 313-9566 | Small FP Mask with (IEC)<br>SE Elbow/with Headgear          | 3139566140807 |  | 2349 | 00841470104689 | 2350 | 10841470104686 |
| 313-9538 | Large RM Mask with (IEC)<br>SE Elbow/with Headgear          | 3139538140516 |  | 2351 | 00841470104580 | 2352 | 10841470104587 |
| 313-9537 | Medium RM Mask with<br>(IEC) SE Elbow/with<br>Headgear      | 3139537140516 |  | 2353 | 00841470104573 | 2354 | 10841470104570 |
| 313-9536 | Small RM Mask with (IEC)<br>SE Elbow / with Headgear        | 3139536140624 |  | 2355 | 00841470104566 | 2356 | 10841470104563 |
| 313-9535 | X Small RM Mask with<br>(IEC) SE Elbow/with<br>Headgear     | 3139535140505 |  | 2357 | 00841470104559 | 2358 | 10841470104556 |

|                                  |                                                      |               |  |      |                |      |                |
|----------------------------------|------------------------------------------------------|---------------|--|------|----------------|------|----------------|
| 313-9548                         | Large RP Mask with (IEC) SE Elbow/with Headgear      | 3139548140616 |  | 3861 | 00841470104870 | 3862 | 10841470104877 |
| 313-9547                         | Medium RP Mask with (IEC) SE Elbow/with Headgear     | 3139547140616 |  | 3863 | 00841470104887 | 3864 | 10841470104884 |
| 313-9546                         | Small RP Mask with (IEC) SE Elbow/with Headgear      | 3139546140617 |  | 2359 | 00841470104894 | 2360 | 10841470104891 |
| <b>BiTrac Mask/Circuit Kits</b>  |                                                      |               |  |      |                |      |                |
| 313-9080                         | 313-9001 W Mask & 313-9075 Circuit                   | 3139080110713 |  | 3472 | NA             | 3473 | NA             |
| 313-9081                         | 313-9002W Mask & 313-9075 Circuit                    | 3139081110713 |  | 3474 | 00841470111663 | 3475 | 10841470111660 |
| 313-9082                         | 313-9003W Mask & 313-9075 Circuit                    | 3139082110713 |  | 3476 | 00841470111670 | 3477 | 10841470111677 |
| 313-9083                         | 313-9004W Mask & 313-9075 Circuit                    | 3139083110713 |  | 3478 | 00841470111632 | 3479 | 10841470111639 |
| 313-9084                         | 313-9054W Mask & 313-9075 Circuit                    | 3139084120313 |  | 3622 | 00841470111649 | 3623 | 10841470111646 |
| 313-9085                         | 313-9052W Mask & 313-9075 Circuit                    | 3139085120313 |  | 3624 | 00841470109424 | 3625 | 10841470109421 |
| 313-9589                         | 313-9501 Mask & 313-9075 Circuit                     | 3139589140826 |  | 2644 | 00841470104740 | 2645 | 10841470104747 |
| 313-9590                         | 313-9502 Mask & 313-9075 Circuit                     | 3139590140826 |  | 2646 | 00841470104757 | 2647 | 10841470104754 |
| 313-9591                         | 313-9503 Mask & 313-9075 Circuit                     | 3139591140826 |  | 2648 | 00841470104764 | 2649 | 10841470104761 |
| 313-9592                         | 313-9504 Mask & 313-9075 Circuit                     | 3139592140826 |  | 2650 | 00841470104771 | 2651 | 10841470104778 |
| <b>BiTrac HC Full Face Masks</b> |                                                      |               |  |      |                |      |                |
| 313-9100                         | Small Twin Lip FF Mask with VAM Elbow /with Headgear | 3139100081030 |  |      | NA             |      | NA             |
| 313-9400                         | Small Twin Lip FF Mask with VAM Elbow /with Headgear | 3139400131118 |  | 3349 | 00841470107451 | 3348 | 10841470107458 |
| 313-9153                         | Small Twin Lip FF Mask with VAM Elbow /with Headgear | 3139153130222 |  |      | NA             |      | NA             |
| 313-9101                         | Med Twin Lip FF Mask with VAM Elbow /with Headgear   | 3139101081030 |  | 7862 | 00841470107567 | 7861 | 10841470107564 |

|          |                                                        |               |  |      |                |      |                |
|----------|--------------------------------------------------------|---------------|--|------|----------------|------|----------------|
| 313-9401 | Med Twin Lip FF Mask with VAM Elbow /with Headgear     | 3139401121106 |  | 3351 | 00841470107420 | 3350 | 10841470107427 |
| 313-9152 | Med Twin Lip FF Mask with VAM Elbow /with Headgear     | 3139152130222 |  |      | NA             |      | NA             |
| 313-9102 | Large Twin Lip FF Mask with VAM Elbow /with Headgear   | 3139102081015 |  | 7860 | 00841470107550 | 7859 | 10841470107557 |
| 313-9402 | Large Twin Lip FF Mask with VAM Elbow /with Headgear   | 3139402131216 |  | 3353 | 00841470107437 | 3352 | 10841470107434 |
| 313-9151 | Large Twin Lip FF Mask with VAM Elbow /with Headgear   | 3139150140226 |  |      | NA             |      | NA             |
| 313-9103 | X Large Twin Lip FF Mask with VAM Elbow /with Headgear | 3139103081030 |  |      | NA             |      | NA             |
| 313-9403 | X Large Twin Lip FF Mask with VAM Elbow /with Headgear | 3139403131118 |  | 3355 | 00841470107444 | 3354 | 10841470107441 |
| 313-9150 | X Large Twin Lip FF Mask with VAM Elbow /with Headgear | 3139150140917 |  |      | NA             |      | NA             |
| 313-9104 | Small Twin Lip FF Mask with VAM Elbow/No Headgear      | 3139104100427 |  | 7872 | 00841470107536 | 7871 | 10841470107533 |
| 313-9404 | Small Twin Lip FF Mask with VAM Elbow/No Headgear      | 3139404141010 |  | 2413 | 00841470107499 | 2414 | 10841470107496 |
| 313-9105 | Med Twin Lip FF -Mask with VAM Elbow /No Headgear      | 3139105100427 |  | 7870 | 00841470107529 | 7869 | 10841470107526 |
| 313-9405 | Med Twin Lip FF -Mask with VAM Elbow /No Headgear      | 3139405141010 |  | 2411 | 00841470107482 | 2412 | 10841470107489 |
| 313-9106 | Large Twin Lip FF Mask with VAM Elbow /No Headgear     | 3139106080923 |  | 7868 | 00841470107512 | 7867 | 10841470107519 |
| 313-9406 | Large Twin Lip FF Mask with VAM Elbow /No Headgear     | 3139406141010 |  | 2409 | 00841470107475 | 2410 | 10841470107472 |

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|-----------|-------------------------------------------------------|---------------|--|------|----------------|------|----------------|
| 313-9107  | X Large Twin Lip FF Mask with VAM Elbow /No Headgear  | TBD           |  | 7866 | 00841470107505 | 7865 | 10841470107502 |
| 313-9407  | X Large Twin Lip FF Mask with VAM Elbow /No Headgear  | 3139407141010 |  | 2407 | 08414170107468 | 2408 | 10841470107465 |
|           | <b><u>Pulmodyne Profit Full Face Masks</u></b>        |               |  |      |                |      |                |
| 313-1001  | Small Profit Full Face Mask w/Standard Headgear       | TBD           |  | 3456 | 00841470111212 | 3457 | 10841470111219 |
| 313-1002  | Medium Profit Full Face Mask w/Standard Headgear      | 18628         |  | 3458 | 00841470111229 | 3459 | 10841470111226 |
| 313-1003  | Large Profit Full Face Mask w/Standard Headgear       | 180912        |  | 3467 | 00841470111236 | 3468 | 10841470111233 |
| 313-1004  | Extra Large Profit Full Face Mask w/Standard Headgear | TBD           |  | 3504 | 00841470111243 | 3505 | 10841470111240 |
| 313-1005  | Small Profit Full Face Mask w/Premium Headgear        | 181023        |  | 3789 | 00841470111250 | 3790 | 10841470111257 |
| 313-1006  | Medium Profit Full Face Mask w/ Premium Headgear      | 180614        |  | 3821 | 00841470111267 | 3822 | 10841470111264 |
| 313-1007  | Large Profit Full Face Mask w/ Premium Headgear       | 180913        |  | 3823 | 00841470111274 | 3824 | 10841470111271 |
| 313-1008  | Extra Large Profit Full Face Mask w/ Premium Headgear | 190222        |  | 3827 | 00841470111281 | 3828 | 10841470111288 |
| 313-9050W | BiTrac Shield                                         | 3139050081007 |  | 3640 | 00841470107024 | 3641 | 10841470107021 |
| 313-9051W | BiTrac Shield SE                                      | 3139051081007 |  | 3642 | 00841470107031 | 3643 | 10841470107038 |
| 313-9052W | Large BiTrac MaxShield                                | 3139052100930 |  | 3628 | 00841470106591 | 3629 | 10841470106598 |
| 313-9053W | Large BiTrac MaxShield SE                             | 3139053100930 |  | 3630 | 00841470106607 | 3631 | 10841470106604 |
| 313-9054W | Small BiTrac MaxShield                                | 3139054100930 |  | 3632 | 00841470106614 | 3633 | 10841470106611 |
| 313-9055W | Small BiTrac MaxShield SE                             | 3139055100930 |  | 3634 | 00841470106638 | 3635 | 10841470106635 |

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|           |                                                                                         |                |  |      |                |      |                |
| 313-9056W | Extra Large BiTrac MaxShield SE                                                         | 3139056W140919 |  | 2652 | 00841470106997 | 2653 | 10841470106994 |
| 313-9057W | Extra Large BiTrac MaxShield                                                            | 3139057W140919 |  | 2654 | 00841470106645 | 2655 | 10841470106642 |
| 313-9552  | Large BiTrac MaxShield (IEC)                                                            | 3139552140527  |  | 2436 | 00841470104603 | 2437 | 10841470104600 |
| 313-9553  | Large BiTrac MaxShield SE (IEC)                                                         | 3139553140505  |  | 2440 | 00841470104610 | 2441 | 10841470104617 |
| 313-9554  | Small BiTrac MaxShield (IEC)                                                            | 3139554140527  |  | 2438 | 00841470104627 | 2439 | 10841470104624 |
| 313-9551  | Small BiTrac MaxShield SE (IEC)                                                         | 3139551140604  |  | 2442 | 00841470104597 | 2443 | 10841470104594 |
| 313-9555  | Extra Large BiTrac MaxShield (IEC)                                                      | 3139555150210  |  | 2712 | 00841470104634 | 2713 | 10841470104631 |
| 313-9556  | Extra Large BiTrac MaxShield SE (IEC)                                                   | 3139556150225  |  | 2714 | 00841470104641 | 2715 | 10841470104648 |
| 313-9557  | BiTrac Select MaxShield with Interchangeable Elbow 22mm Female, and Head Strap, Small   | 180504         |  | 4154 | 00841470111557 | 4175 | 10841470111554 |
| 313-9558  | BiTrac Select MaxShield with Interchangeable Elbow 22mm Female, and Head Strap, LARGE   | 180504         |  | 4187 | 00841470111540 | 4190 | 10841470111547 |
| 313-9559  | BiTrac Select MaxShield with Interchangeable Elbow 22mm Female, and Head Strap, X LARGE | 180607         |  | 4192 | 00841470111533 | 4194 | 10841470111530 |
| 313-9524  | XXS BiTrac MaxShield Select Pediatric w/Standard Elbow                                  | 3139524171208  |  | 3446 | 00841470111090 | 3509 | 10841470111097 |
| 313-9525  | XS BiTrac MaxShield Select Pediatric w/Standard Elbow                                   | 3139525171208  |  | 3511 | 00841470111083 | 3597 | 10841470111080 |
| 313-9526  | XXS BiTrac MaxShield Select Pediatric w/AA Leak Elbow                                   | 3139526171222  |  | 3222 | 00841470110918 | 3223 | 10841470110915 |
| 313-9527  | XS BiTrac MaxShield Select Pediatric w/AA Leak Elbow                                    | 3139527171222  |  | 3226 | 00841470110925 | 3227 | 10841470110922 |

## BiTrac Mask Full Face Mask Accessories

|          |                                                  |               |  |      |                |      |                |
|----------|--------------------------------------------------|---------------|--|------|----------------|------|----------------|
| 313-9117 | FF Mask Cone - Small                             | 3139117140109 |  |      | NA             |      | NA             |
| 313-9118 | FF Mask Cone - Medium                            | 3139118090311 |  |      | NA             |      | NA             |
| 313-9119 | FF Mask Cone - Large                             | 3139118140109 |  |      | NA             |      | NA             |
| 313-9120 | FF Mask Cone - X Large                           | 3139120140109 |  |      | NA             |      | NA             |
| 313-9121 | FF Mask Snap Ring- Small                         | TBD           |  |      | NA             |      | NA             |
| 313-9122 | FF Mask Snap Ring - Medium                       | TBD           |  |      | NA             |      | NA             |
| 313-9123 | FF Mask Snap Ring - Large                        | TBD           |  |      | NA             |      | NA             |
| 313-9124 | FF Mask Snap Ring -- X Large                     | TBD           |  |      | NA             |      | NA             |
| 313-9125 | FF Mask Cushion/Ring - Small                     | 3139125140109 |  |      | NA             |      | NA             |
| 313-9126 | FF Mask Cushion/Ring - Medium                    | 3139126140109 |  |      | NA             |      | NA             |
| 313-9127 | FF Mask Cushion/Ring - Large                     | 3139127080923 |  |      | NA             |      | NA             |
| 313-9128 | FF Mask Cushion/Ring - X Large                   | 3139128140109 |  |      | NA             |      | NA             |
| 313-9599 | Standard (SE) Interchangeable Elbow              | 3139599140501 |  | 3877 | 00841470109363 | 3878 | 10841470109360 |
| 313-9598 | Anti-Asphyxia Interchangeable Elbow              | 3139598140501 |  | 3879 | 00841470109370 | 3880 | 10841470109377 |
| 313-9597 | Standard (SE) Bronchoscopy Interchangeable Elbow | 3139597141125 |  | 2710 | 00841470104801 | 2711 | 10841470104808 |
| 313-9596 | Anti-Asphyxia Bronchoscopy Interchangeable Elbow | 3139596141211 |  | 2727 | 00841470109417 | 2728 | 10841470109414 |
| 313-9595 | Standard (SE) Nebulizer Interchangeable Elbow    | 3139595140620 |  | 2598 | 00841470109431 | 2599 | 10841470109438 |
| 313-9594 | Anti-Asphyxia Nebulizer Interchangeable Elbow    | 3139594140620 |  | 2601 | 00841470109394 | 2602 | 10841470109391 |
| 313-9593 | Anti-Asphyxia with Leak Interchangeable Elbow    | 3139593140514 |  | 2324 | 00841470110628 | 2325 | 10841470110625 |
| 313-9601 | Pediatric SE Elbow                               | 180917        |  | 3714 | 00841470111687 | 3715 | 10841470111684 |
| 313-9602 | Pediatric AA w/Leak Elbow                        | 181011        |  | 3718 | 00841470111694 | 3719 | 10841470111691 |
| 313-4948 | Adapter 22mm Female X 30mm Female                | 3134948180712 |  | 3276 | 00841470111625 | 3277 | 10841470111622 |

|          |                                          |               |  |      |                |      |                |
|----------|------------------------------------------|---------------|--|------|----------------|------|----------------|
| 313-9185 | ADAPT-2-VENT 30mmF<br>BiTrac ED AA Elbow | 3139185180612 |  | 2012 | 00841470110857 | 3135 | 10841470110854 |
| 313-9186 | ADAPT-2-VENT 30mmF<br>BiTrac ED SE Elbow | 180731        |  | 2099 | 00841470111571 | 2100 | 10841470111578 |
| 313-5072 | Large. Headgear- Full Cap-<br>White      | 3135072100309 |  |      | NA             |      | NA             |
| 313-5073 | Large. Headgear- Full Cap-<br>Black      | TBD           |  |      | NA             |      | NA             |
| 313-5074 | Med. Headgear- Full Cap-<br>White        | TBD           |  |      | NA             |      | NA             |
| 313-5075 | Med. Headgear- Full Cap-<br>Black        | TBD           |  |      | NA             |      | NA             |
| 313-5076 | White "H" Strap Reusable                 | TBD           |  |      | NA             |      | NA             |
| 313-5077 | Black "H" Strap Reusable                 | TBD           |  |      | NA             |      | NA             |
| 313-5078 | Headgear Chin Strap                      | TBD           |  | NA   | NA             | 6490 | 10841470110311 |
| 313-9149 | Head Strap w/4 Clips                     | 3139149150317 |  |      | NA             |      | NA             |
| 313-7826 | Head Strap w/ 2 Clips                    | TBD           |  |      | NA             |      | NA             |
| 313-6907 | Headgear Washing Bag                     | TBD           |  |      | NA             |      | NA             |
| 313-6908 | Travel Bag                               | TBD           |  |      | NA             |      | NA             |
| 313-8344 | Large MaxShield Headgear                 | 3138344151026 |  | 2866 | 00841470103101 | 2867 | 10841470103108 |
| 313-8347 | Small MaxShield Headgear                 | 3138347151026 |  | 2868 | 00841470103118 | 2869 | 10841470103115 |
| 313-9528 | XXS Pediatric MaxShield<br>Headgear      | 180124        |  | 3720 | 00841470111175 | 3721 | 10841470111172 |
| 313-9529 | XS Pediatric Headgear                    | 180124        |  | 3722 | 00841470111182 | 3723 | 10841470111189 |
| 313-9146 | Profit Standard Headgear                 | 3139146111019 |  | 7953 | NA             | 7954 | NA             |
| 313-6906 | Profit Premium Headgear                  | TBD           |  |      | NA             |      | NA             |