

Bio-Medical Devices International, Inc. (Bio-Medical Devices Intl, BMDI) is an active, privately owned, small business that filed as a California Corporation on 01 June 1998.

California Corporations Entity Number C2087350.  
TIN: 33-0855847  
DUNS: 796519903

BMDI Headquarters are located at 17171 Daimler Street, Irvine, CA.

BMDI is the exclusive distributor of the MAXAIR<sup>®</sup> line of Powered Air Purifying Respirators (PAPRs), manufactured by Syntech International (Irvine, CA) and Syntech de Baja (Tijuana, Mexico). Both manufacturing operations are under the same ownership group as BMDI.

BMDI distributes the MAXAIR Systems line via a number of Independent Manufacturer's Representatives (IMRs) in various healthcare markets, and several Distributors in other select markets, in the U.S.A., and via distributors in similar markets internationally.

BMDI's name reference to biomedical devices (Bio-Medical Devices) is reference to the primary, but not exclusive, market segments addressed by the MAXAIR PAPR line; no correlation is, to date, intended for the classification of the products.

MAXAIR Systems are, more specifically, considered and classified as loose fitting, helmet, and hood, particulate filtering PAPRs, by those agencies that are directly involved with respirator standards and approvals. No MAXAIR Systems configurations are currently classified as medical devices.

In the U.S.A., The National Institute for Occupational Safety and Health (NIOSH), under authorization of the Occupational Safety and Health Act of 1970, provides a testing, approval, and certification program assuring respirators used in the workplace meet the standards of 42 CFR Part 84.

To date, the FDA (Food and Drug Administration) has not chosen to approve or regulate PAPRs.

As a NIOSH respirator approval is provided to the manufacture of the respirator, MAXAIR Systems PAPRs are approved under the name Syntech International. A current list of NIOSH approved PAPRs is provided on-line by the "Certified Equipment List Search" ([https://www2a.cdc.gov/drds/cel/cel\\_form\\_code.asp](https://www2a.cdc.gov/drds/cel/cel_form_code.asp)) . MAXAIR Systems specific listings may be found from that website page by selecting "Syntech International" in the Manufacture search box, and then clicking on "View Results" at the bottom of the search page (see next page, Exhibit 1). For example, MAXAIR listings as of 8/16/2016 are as indicated on the next page, Table 1.

BMDI Marketing

Instructions and Tips  
 General Cautions and Limitations  
 Definitions of Terms  
 Prior Manufacturers Names

**Certified Equipment List Search**  
[Query Form Instructions and Tips](#)

**Quick Searches**  
 To use the quick search feature, simply select the type of respirator.

Respirators Providing CBRN Protection

- CBRN Self-Contained Breathing Apparatus (SCBA)
- CBRN Air Purifying Respirators (CBRN/APR)
- CBRN Air Purifying Respirators (CBRN/APER)
- CBRN Powered Air Purifying Respirators (CBRN/PAPR)

[View Quick Results](#)

**Define your own Search**  
 To define your own search, select criteria from the following lists  
 reset button to clear the form for new searches.

Maximum Number of Records Returned in a Set

Schedule

13F - Self-Contained Breathing Apparatus (SCBA)  
 14G - Gas Masks  
 19C - Supplied-Air Respirators (SAR)  
 21C - Particulate Respirators

- Combination Air-Purifying/Atmosphere-Supplying
- Combination Gas/Vapor Removing and Particulate Filtering
- Gas/Vapor Removing
- Particulate Filtering
- Combination SCBA/SAR

For Protections Against:

Abrasive Blasting  
 Acid Gas  
 Ammonia  
 Asbestos-containing dusts and mists, however, no longer pe

Manufacturer

Syntech International  
 The Lincoln Electric Company  
 Valmy SAS

**Exhibit 1.**

**Table 1.**

**Certified Equipment List**

**CEL Results**  
 Selection Criteria  
 Manufacturer(s)  
 Syntech International  
 Do NOT Include Obsolete Respirators

Schedule	Approval #	Manufacturer		
21C	0812	Syntech International	Maxair PAPR with Tri-Snap Helmet	Helmet
21C	0813	Syntech International	Maxair PAPR with Single Post Helmet	Helmet
21C	0849	Syntech International	Maxair Loose Fitting Universal CH Helmet Power Air Purifying Respirator	Helmet
21C	0850	Syntech International	Maxair Series Powered Air Purifying Respirator with Universal CH Helmet	Helmet
21C	0851	Syntech International	Maxair Series Powered Air Purifying Respirator with Universal CH Helmet	Helmet
21C	0911	Syntech International	Maxair Loose Fitting Helmet Powerd Air Purifying Respirator with the Universal-CH Helmet	Helmet
21C	0912	Syntech International	Maxair Loose Fitting Helmet Powered Air Purifying Respirator with the Universal-CH Helmet	Helmet
21C	0915	Syntech International	Maxair Powered Air Purifying Respirator with Loose Fitting Helmet	Helmet
21C	0942	Syntech International	Model Maxair Loose Fitting Powered Air Purifying Respirator with Helmet and Filter	Helmet
21C	0946	Syntech International	Model MaxAir Loose Fitting Helmet Powerd Air Purifying Respirator	Helmet
21C	0960	Syntech International	MaxAir Loose Fitting Powered Air Purifying Respirator with the HE DLC Hood	Hood
21C	0961	Syntech International	MaxAir Loose Fitting Powered Air Purifying Respirator with HE DLC Hood	Hood



Hector Garcia <hector.garcia1@co.hidalgo.tx.us>

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## RE: MAXAIR Systems

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Ken Arthur <karthur@biomaxair.com>

Tue, Jun 30, 2020 at 4:31 PM

To: Hector Garcia <hector.garcia1@co.hidalgo.tx.us>, William Kirk <dkirk@biomaxair.com>

Hector,

The Maxair Systems product line is only sold directly to the end user by Bio-Medical Devices Int'l (BMDI). MedTechMedCare (MTMC) is simply a national independent rep company, and a few of their reps sell the Maxair line in different areas. We only sell to the healthcare marketplace through independent sales agents. MTMC is not a reseller, and all POs would go to BMDI. Our pricing is fixed on a volume-based scenario. Also, all invoices will come from BMDI.

You should have this already from Sergio, or another version perhaps, but see attached Sole Source letter. Hope this helps clarify things. Please let Sergio and I know how else we can help you.

Ken

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**Ken Arthur**  
**Director of Sales - West**  
**Mobile: 713.409.8567**  
**karthur@biomaxair.com**



[www.Maxair-systems.com](http://www.Maxair-systems.com)

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**From:** Hector Garcia <hector.garcia1@co.hidalgo.tx.us>

**Sent:** Tuesday, June 30, 2020 2:25 PM

**To:** William Kirk <dkirk@biomaxair.com>

**Cc:** Ken Arthur <karthur@biomaxair.com>

**Subject:** Re: MAXAIR Systems

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**Sole Source Documentation 091218.docx**

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