



博辉瑞进医用防护服/隔离衣产品介绍

Medical Protective Coverall Information

BH800: Type 3 Conform to EN14126 EN14605/466

BH500: Type 5 Conform to EN14126 EN13982



- 企业简介 Company Profile
- 产品标准符合性介绍 Introduction to product standard compliance
- 产品性能介绍 Introduction of product performance
- 产品包装信息 Product packaging information
- 产品国内资质 Domestic certification of product
- 产品CE资质 CE certification of product
- 产品FDA资质 FDA certification of product
- 产品出口证明 Product export certification

企业简介：提供组织修复和微创外科先进的全面解决方案



企业基本情况

- III类无菌植入性医疗器械
- 自主知识产权（专利88项，国外专利19项）
- 生产面积5000m²；研发中心面积2000m²
- 国家药监局注册证25项，CE注册证18项，FDA注册证10项

资质荣誉

- 承担国家发改委“药谷一号”生物医药公共服务平台
- 承担“十二五”新材料领域国家重点研发计划（863）课题
- 获2018年中关村国家自主创新示范区高精尖产业培育项目资助
- 国家高新技术企业，中关村高新技术企业，北京市企业科技研发机构
- 博士后科研工作站
- 北京市新技术新产品，获省级科技进步二等奖
- 北京市专利试点单位，国家知识产权局审查员实习基地
- “科创板潜力公司百强”、“2018中国最具投资价值企业50强”、“2019年最具创新力企业”

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Company Profile



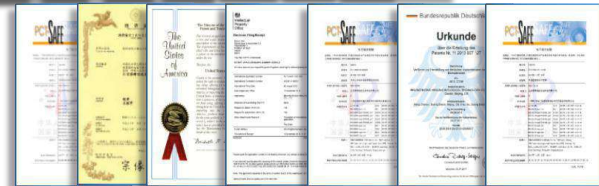
Overview

- Founded in June, 2012, authorized manufacture for Class III implantable medical devices
- Production area : 5000m² including of 2500m² GMP workshop
- R&D center: 2000m²
- 25 NMPA Certificates, 18 CE Certificates, 10 FDA Certificates
- 88 authorized national patents



Honors

- **National Key R&D Program (The No. 863)** in the new material project of the Ministry of Science and Technology
- The Biomedical Incubation Platform financed by **the National Development and Reform Commission**
- The top 50 of **the Most Investment-Worthy Companies in China**
- Top 100 **Creative Potential Companies** in Chinese capital market



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生产车间 Workshop



5000m²生产面积，2500m²GMP万级洁净车间 (5000m² Production area , 2500m² GMP workshop)

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博辉瑞进生产防疫物资媒体报道 Media Interview



北京博辉瑞进生物科技有限公司董事长接受中央电视台的采访

The president of Beijing Biosis Healing Biological Technology Co.,Ltd was interviewed by China Central Television (CCTV)



北京市领导赴北京博辉瑞进生物科技有限公司视察防护物资产品生产工作

The Beijing Market Supervision Medical Devices Administration came to visit Beijing Biosis Healing Biological Technology Co.,Ltd for the production of protective products



北京博辉瑞进生物科技有限公司COO接受北京电视台的采访

The COO of Beijing Biosis Healing Biological Technology Co.,Ltd was interviewed by Beijing Television (BTV)

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产品标准符合性介绍 Introduction to product standard compliance



产品型号 Product Model	符合中国标准 Standard CN	符合欧盟标准 Standard EU	符合美国标准 Standard US	适用范围 scope of application
Medical Protective Coverall-BH800	GB 19082-2009	EN14126 EN14605/466 ejection compact Coverall Type3	ASTM F1670-98 ASTM F1671-97A ASTM F903-1999 AAMI PB-70 Medical Protective Clothing	防止医护人员接触空气或液体中的病毒和细菌 For preventing the medical staffs from virus and other germs in air or liquid
Medical Protective Coverall-BH500	京大械备 20200017	EN14126 dust compact EN13982 ISO 13982-1 Coverall Type5	AAMI PB-70 Isolation Gown	用于医疗机构门诊、病房、检验室等作普通隔离。 Used for general isolation in out-patient, ward and laboratory of medical institution.

如其他国家要关注技术参数，需要同时满足：

- 1、通过相当 N14126 防护标准的测试
- 2、通过相当 EN14605、EN13982、EN13034-1&2 标准的测试；

Please noted specifications for some other countries :

1. Passed the test equivalent to EN14126 protection standard
2. Passed the test equivalent to EN14605、EN13982、EN13034-1&2 protection standard

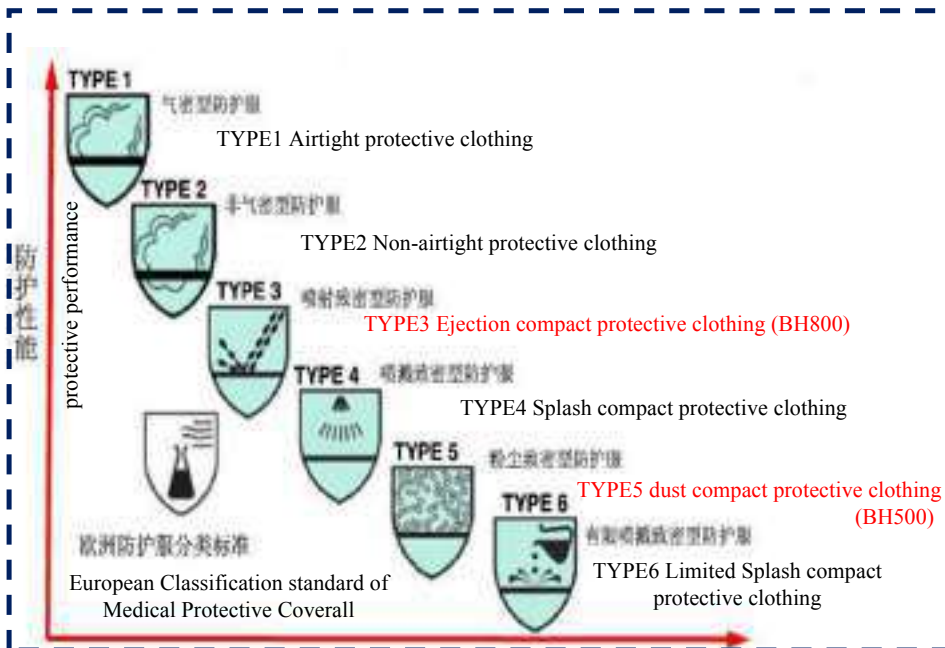


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产品标准符合性介绍 Introduction to product standard compliance



防护服欧标分类 European Classification standard of Medical Protective Coverall



1、防护等级要求较高的场所，譬如ICU、重症隔离病房等级别要求高的地方，使用Type4及以上级别的防护（即：可使用Type4、Type3的防护服）
欧标符合情况：Type3和 Type4符合EN14126 和 EN14605、EN13982、EN13034-1&2

Application: Type4 Level and above Level Medical Protective Coverall can be used in the places with higher levels of protection(e.g: ICU Isolation Approach)

European Standard : Type3 and Type4 accord with EN14126、EN14605、EN13982 、EN13034-1&2。

2、防护等级相对较低的场所，如发热门诊、普通隔离病区等，使用 TYPE5、Type6的防护服。

欧标符合情况：

Type5符合EN14126 和 EN13982、EN13034-1&2；

Type6符合EN14126 和 EN13034-1&2。

Application: Type5 Level and Type6 Level Medical Protective Coverall can be used in the places with relatively low levels of protection (e.g: Fever Clinics, General Isolation Approach)

European Standard :

Type5 accord with EN14126、EN13982、EN13034-1&2；

Type6 accord with EN14126 、EN13034-1&2

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 BIOSIS HEALING
博辉瑞进

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$\mathbb{R}^n \subseteq \mathbb{R}^m$

属性	测试方法	结果	标准
防静电(内层, 25%)	GB12014	$0.7 \times 10^9 \Omega$	符合
防静电(外层, 25%)	GB12014	$9.5 \times 10^9 \Omega$	符合

 BIOSIS HEALING
博辉瑞进

The diagram shows a full-body protective suit with the following features highlighted by callouts:

- Self-cleaning (200 to 300 times) for each use.** (Pointing to the upper chest area)
- Self-cleaning (200 to 300 times) for each use.** (Pointing to the lower chest area)
- Self-cleaning (200 to 300 times) for each use.** (Pointing to the upper arm area)
- Self-cleaning (200 to 300 times) for each use.** (Pointing to the lower arm area)
- Self-cleaning (200 to 300 times) for each use.** (Pointing to the leg area)
- Self-cleaning (200 to 300 times) for each use.** (Pointing to the foot area)



State	Height (cm)	Feet (inches)	Feet (meters)	Feet (meters)	Feet (meters)
100	165 + 3	123	94	18	24
100	163 + 1	125	98	18	24
170	173 + 1	138	90	18	24
175	176 + 4	136	91	18	24
180	180 + 5	142	96	18	26
185	185 + 5	145	99	18	24
190	190 + 5	145	99	18	24

Follow the following instructions:

 Springer

BH500型隔离衣产品性能介绍



本产品采用医用级无纺布为主要原料，经特殊工艺制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。

【适用范围】用于手术室内门、病室、检查室等产生污染源。

【产品特点】

1. 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。

1. 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。

1. 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。



1. 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。



【优点】

- 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。
- 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。
- 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。
- 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。

【包装】

每包4件，独立包装。

【适用范围】

适用于手术室内门、病室、检查室等产生污染源。

【规格】

规格分为S-160, M-165, L-170, XL-175, XXL-180, XXXL-185。

规格分为S-160, M-165, L-170, XL-175, XXL-180, XXXL-185。

【尺码对照表】

型号	身高 (+5CM)	身高 (+10CM)
S-160	165	170
M-165	165	175
L-170	170	180
XL-175	175	185
XXL-180	180	190
XXXL-185	185	195



1. 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。



1. 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。



1. 采用医用级无纺布制成，具有优异的阻隔性能，能够有效防止液体、颗粒、细菌、病毒、真菌、霉菌、孢子等污染物的渗透，确保穿着者的安全。

【性能指标】

项目	测试方法	标准	结果
阻隔性能	GB/T 16881.1	≥100000	符合
阻隔性能	GB/T 16881.2	≥100000	符合
阻隔性能	GB/T 16881.3	≥100000	符合
阻隔性能	GB/T 16881.4	≥100000	符合
阻隔性能	GB/T 16881.5	≥100000	符合
阻隔性能	GB/T 16881.6	≥100000	符合
阻隔性能	GB/T 16881.7	≥100000	符合
阻隔性能	GB/T 16881.8	≥100000	符合
阻隔性能	GB/T 16881.9	≥100000	符合
阻隔性能	GB/T 16881.10	≥100000	符合

【性能指标】

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阻隔性能	GB/T 16881.4	≥100000	符合
阻隔性能	GB/T 16881.5	≥100000	符合
阻隔性能	GB/T 16881.6	≥100000	符合
阻隔性能	GB/T 16881.7	≥100000	符合
阻隔性能	GB/T 16881.8	≥100000	符合
阻隔性能	GB/T 16881.9	≥100000	符合
阻隔性能	GB/T 16881.10	≥100000	符合

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阻隔性能	GB/T 16881.3	≥100000	符合
阻隔性能	GB/T 16881.4	≥100000	符合
阻隔性能	GB/T 16881.5	≥100000	符合
阻隔性能	GB/T 16881.6	≥100000	符合
阻隔性能	GB/T 16881.7	≥100000	符合
阻隔性能	GB/T 16881.8	≥100000	符合
阻隔性能	GB/T 16881.9	≥100000	符合
阻隔性能	GB/T 16881.10	≥100000	符合

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阻隔性能	GB/T 16881.4	≥100000	符合
阻隔性能	GB/T 16881.5	≥100000	符合
阻隔性能	GB/T 16881.6	≥100000	符合
阻隔性能	GB/T 16881.7	≥100000	符合
阻隔性能	GB/T 16881.8	≥100000	符合
阻隔性能	GB/T 16881.9	≥100000	符合
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阻隔性能	GB/T 16881.7	≥100000	符合
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 BIOSIS HEALING
博辉瑞进

[underlining principle]

The material is subjected to secondary coating treatment on the surface of high-density polypropylene long fiber heat-sealed non-woven fabric to form a high-strength, chemical-resistant, and penetration isolation protective layer.



It effectively filters and blocks the penetration of dusts, bacteria and other harmful substances in the air



Free trial

- Access the toxin transmembrane by OSMOR.
- Increased water resistance: Synthetic blood substitutes (hemolysis, surface membrane resistance, to prevent protein effluxes)
- Cells produced with a clear protective shell (nanoparticles)
- It contains internal receptors in lipid phospholipids and a protein coat, phospholipid, hydrophobic, easy to be degraded, non-toxic and non-infectious, etc.
- High stability after low temperatures
- High strength and flexibility (stable in low solutions)
- Chemical resistance: Not affected by the action of organic solvents
- Thermal stability: Stable at high and low temperatures, high thermal stability and low thermal conductivity
- High capacity resistance from their structure to enhance resistance to stress



File name:

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[Application]

Grand 44 is a great all-around tool for working on virtually every size engine, from the smallest vintage cars to the latest.

Classification and use

Model	Height (mm)	Clamp distance
S-160	165	128
SR-181	188	150
S-170	175	138
S-175	176	139
S20-185	185	148
S22-189	189	149

1993, 1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 26



7. Each participant is given 10 to 15 minutes to complete the survey and then the survey is collected.



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Journal of Internal Medicine 255: 103–110

Beijing Sixin Healing Biological Technology Co., Ltd.
Address: No.6 plant west, Valley No.1 Bio-medicine
Industry Park, Daxing
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Tel: +86-10-84625450 Fax: +86-10-64625457
Web: www.sixinhealing.com
Email: info@sixinhealing.com

 manifest
 batch number
  Refer to the operating instructions
  warning

产品包装信息 Product packaging information



产品 Picture	品名 Product Name	型号 Model	每箱数量 Carton volume (pcs/box)	外箱尺寸 Carton Dimension (mm)	毛重 Carton G.W (kg)
	Medical Protective Coverall-BH800	S M L XL	25	480x450x415mm	9.86
	Medical Protective Coverall-BH500	S M L XL	25	480x450x415mm	8.32

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产品包装信息 Product packaging information



托盘体积：95x95x187cm（总高度，不含蓝色底盘）；

Tray volume: 95x95x187cm (total height, excluding blue chassis);

外箱尺寸：480x450x415mm,航空重量15kg,每箱尺寸为0.09m³,16箱为一托盘，合计1.44m³;

Outer box size: 480x450x415mm, aviation weight of 15kg, each box size is 0.09m³, 16 boxes are a tray, total 1.44m³;

货柜：20尺货柜，可装310箱，40尺货柜可装610箱。

Container: 20 feet container, can hold 310 boxes, 40 feet container can hold 610 boxes.

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产品国内资质 Product domestic certification



一次性医用防护服医疗器械注册证 Medical device registration certificate of disposable Medical Protective Coverall-BH800

京械注准 20202140241
Beijing medical device registration approval
No.20202140241

中华人民共和国医疗器械注册证

注册证编号：京械注准20202140241

注册人名称	北京博辉瑞进生物科技股份有限公司
注册人住所	北京市昌平区中关村科技园回龙观生物医药园昌平生物医药产业基地一期B11号博辉瑞进厂房B座
生产地址	北京市昌平区中关村科技园回龙观生物医药园昌平生物医药产业基地一期B11号B座5层、北京市昌平区中关村科技园回龙观生物医药产业基地二期B11号B座5层
注册人名称	北京博
注册人住所	北京市
产品名称	一次性医用防护服
型号、规格	160、165、170、175、180、185
结构及组成	防护服由衣身、袖套、裤腿、鞋套、手套等组成。防护服由衣身、袖套、裤腿、鞋套、手套等组成。防护服由衣身、袖套、裤腿、鞋套、手套等组成。
适用范围	适用于在医疗机构内从事诊疗活动的医务人员使用。适用于在医疗机构内从事诊疗活动的医务人员使用。适用于在医疗机构内从事诊疗活动的医务人员使用。
附件	产品技术要求
其他内容	
备注	

北京市市场监督管理局



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隔离衣医疗器械备案证
Medical device recordation certificate of Medical
Protective Coverall-BH500

京大械备 20200017
Beijing Daxing medical device recordation
certificate number
No.20200017

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产品国内资质 Product domestic certification



一次性医用防护服/隔离衣生产许可证 Production licence of disposable Medical Protective Coverall



生产许可证信息 (续前)				
序号	产品名称	生产号	发证日期	备注
1	医用防护服	10000000000000000000	2020.10.10	—
生产许可证信息 (续前)				
2	医用防护服	10000000000000000000	2020.10.10	—
3	医用防护服	10000000000000000000	2020.10.10	—
4	医用防护服	10000000000000000000	2020.10.10	—
5	医用防护服	10000000000000000000	2020.10.10	—
6	医用防护服	10000000000000000000	2020.10.10	—
7	医用防护服	10000000000000000000	2020.10.10	—
8	医用防护服	10000000000000000000	2020.10.10	—
9	医用防护服	10000000000000000000	2020.10.10	—
10	医用防护服	10000000000000000000	2020.10.10	—
11	医用防护服	10000000000000000000	2020.10.10	—
12	医用防护服	10000000000000000000	2020.10.10	—
13	医用防护服	10000000000000000000	2020.10.10	—
14	医用防护服	10000000000000000000	2020.10.10	—
15	医用防护服	10000000000000000000	2020.10.10	—

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产品国内资质 Product domestic certification



BH800医用防护服中国标准GB19082-2009检测报告/ GB19082-2009 test report for Medical Protective Coverall - BH800

国家食品药品监督管理局北京医疗器械质量监督检验中心
检测报告首页

报告编号	2014-11-11	报告日期	2014-11-11
产品名称	医用防护服	规格型号	1号
申请人	北京博粹诺进医疗器械有限公司	受托单位	北京博粹诺进医疗器械有限公司
委托方	北京博粹诺进医疗器械有限公司	检测项目	GB19082-2009
检测依据	GB19082-2009	检测方法	GB19082-2009
检测结果	合格	检测结论	合格
检测日期	2014-11-11	检测地点	北京博粹诺进医疗器械有限公司
检测人员	张明	审核人员	张明
检测单位	北京博粹诺进医疗器械有限公司	检测地址	北京博粹诺进医疗器械有限公司

国家食品药品监督管理局北京医疗器械质量监督检验中心
检测报告

报告编号	2014-11-11	报告日期	2014-11-11
产品名称	医用防护服	规格型号	1号
申请人	北京博粹诺进医疗器械有限公司	受托单位	北京博粹诺进医疗器械有限公司
委托方	北京博粹诺进医疗器械有限公司	检测项目	GB19082-2009
检测依据	GB19082-2009	检测方法	GB19082-2009
检测结果	合格	检测结论	合格
检测日期	2014-11-11	检测地点	北京博粹诺进医疗器械有限公司
检测人员	张明	审核人员	张明
检测单位	北京博粹诺进医疗器械有限公司	检测地址	北京博粹诺进医疗器械有限公司

国家食品药品监督管理局北京医疗器械质量监督检验中心
检测报告

报告编号	2014-11-11	报告日期	2014-11-11
产品名称	医用防护服	规格型号	1号
申请人	北京博粹诺进医疗器械有限公司	受托单位	北京博粹诺进医疗器械有限公司
委托方	北京博粹诺进医疗器械有限公司	检测项目	GB19082-2009
检测依据	GB19082-2009	检测方法	GB19082-2009
检测结果	合格	检测结论	合格
检测日期	2014-11-11	检测地点	北京博粹诺进医疗器械有限公司
检测人员	张明	审核人员	张明
检测单位	北京博粹诺进医疗器械有限公司	检测地址	北京博粹诺进医疗器械有限公司

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产品国内资质 Product domestic certification



商务部医疗物资出口白名单 (The white list of ministry of commerce medical products export)

省级药监部门医用防护服注册信息				
59	56	津械注准20172640205	一次性医用防护服	天津市远航工贸发展有限公司
60	57	津械注准20202140805	一次性医用防护服	天津奔鹭服饰有限公司
61	58	津械注准20202140807	一次性医用防护服	天津市睿远科技有限公司
62	59	津械注准20202140809	一次性医用防护服	陈华(天津)新能源投资有限公司
63	60	京械注准20202140027	医用一次性防护服	北京邦维高科特种纺织品有限责任公司
64	61	京械注准20202140056	医用一次性防护服	依文服饰股份有限公司
65	62	京械注准20202140061	医用一次性防护服	雅源朗迪(北京)科技发展股份有限公司
66	63	京械注准20202140067	医用一次性防护服	北京赢冠口腔医疗科技股份有限公司
67	64	京械注准20202140071	医用一次性防护服	北京万生人和科技有限公司
68	65	京械注准20202140059	医用一次性防护服	依文服饰股份有限公司
69	66	京械注准20202140091	一次性医用防护服	北京博辉瑞进生物科技有限公司
70	67	鲁械注准20172640283	医用一次性防护服	山东康力医疗器械科技有限公司
71	68	鲁械注准20182640008	医用一次性防护服	山东九尔实业集团有限公司
72	69	鲁械注准20182640065	医用防护服	山东省聚成医疗器械有限公司
73	70	鲁械注准20202140108	医用一次性防护服	山东朱氏药业集团有限公司
74	71	鲁械注准20202140109	医用一次性防护服	日照三奇医疗卫生用品有限公司
新冠病毒检测试剂 呼吸机 医用防护服 医用防护口罩 医用外科口罩 一次性使用医用口罩 红外热...				

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产品国内资质 Product domestic certification



中国医药保健品进出口商会医疗物资出口白名单 (The white list of medical devices of China Chamber Of Commerce Of Medicines & Health Products Importers & Exporters)

取得国外标准认证或注册的医疗物资生产企业清单			
Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries			
动态更新: 2020年5月15日 下载			
序号	生产企业	统一社会信用代码	国外注册 认证情况
二。	医用防护服 Medical Protective Gowns		
87	北京博晖瑞进生物科技有限公司 Beijing Biosis Healing Biological Technology Co., Ltd	91110115596057832U	欧盟CE

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产品CE资质 CE certification of product

ISO 和 CE一致性声明 (ISO & CE Declaration of Conformity)



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产品CE资质 CE certification of product



BH800 防护服EN14605检测报告/ EN14605 Test report for Medical Protective Coverall-BH800

cttc 检测中心
TEST REPORT

Page 1 of 2

Report No.	BH800-2023-001	Test Type	EN14605
Manufacturer	Biosis Healing Technology Co., Ltd.	Client	JetPro AG
Sample Name	Medical Protective Coverall-BH800	Order Number	BH800-01
Tested Item	Medical Protective Coverall	Test Result	Pass
Test Method	EN 14605:2005	Test Date	2023-01-10



Reported By: [Signature]
Reported Date: 2023-01-10

Test Result: Pass

cttc 检测中心
TEST REPORT

Page 2 of 2

Item	Requirement (EN14605)	Result	Pass/Fail	Test Method
Material permeability	< 0.1	< 0.001	Pass	EN14605:2005
Waterproofing	> 1000	> 1000	Pass	EN14605:2005
Sealing strength	> 100	> 100	Pass	EN14605:2005
Flame retardant	< 10	< 10	Pass	EN14605:2005
Acid resistance	> 100	> 100	Pass	EN14605:2005
Alkali resistance	> 100	> 100	Pass	EN14605:2005
UV resistance	> 100	> 100	Pass	EN14605:2005
Oil resistance	> 100	> 100	Pass	EN14605:2005
Heat resistance	> 100	> 100	Pass	EN14605:2005
Low temperature resistance	> 100	> 100	Pass	EN14605:2005

Test Result: Pass

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产品CE资质 CE certification of product



BH500 防护服EN14126检测报告/ EN14126 Test report for Medical Protective Coverall-BH500

SGS

Test Report No. 20230410000176 Date Recd 10.10.2023 Page 1 of 1

Client: BIOSIS HEALING, R & D Center, TONGJIAO, CHINA

Product: Medical Protective Coverall

Standard: EN14126:2011

Test Results: Pass

Signature: [Signature]

SGS

Test Report No. 20230410000176 Date Recd 10.10.2023 Page 2 of 1

Product: Medical Protective Coverall

Standard: EN14126:2011

Test Results: Pass

Signature: [Signature]

SGS

Test Report No. 20230410000176 Date Recd 10.10.2023 Page 3 of 1

Product: Medical Protective Coverall

Standard: EN14126:2011

Test Results: Pass

Signature: [Signature]

SGS

Test Report No. 20230410000176 Date Recd 10.10.2023 Page 4 of 1

Product: Medical Protective Coverall

Standard: EN14126:2011

Test Results: Pass

Signature: [Signature]



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BH500 防护服REACH检测报告/ REACH Test report for Medical Protective Coverall-BH500

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SGS		
1st. Name: <u>SGS Global Services SA</u> 2nd. City: <u>CH-1220</u> Phone: <u>0041 22 349 61 00</u> Account: <u>Head Office</u> 3rd. City: <u>CH-1220</u> Postal/Zip: <u>1220</u> Telephone: <u>0041 22 349 61 00</u> 4th. City: <u>CH-1220</u> Mobile: <u>0041 79 300 00 00</u> 5th. City: <u>CH-1220</u> 6th. City: <u>CH-1220</u> 7th. City: <u>CH-1220</u> 8th. City: <u>CH-1220</u> 9th. City: <u>CH-1220</u> 10th. City: <u>CH-1220</u> 11th. City: <u>CH-1220</u> 12th. City: <u>CH-1220</u> 13th. City: <u>CH-1220</u> 14th. City: <u>CH-1220</u> 15th. City: <u>CH-1220</u> 16th. City: <u>CH-1220</u> 17th. City: <u>CH-1220</u> 18th. City: <u>CH-1220</u> 19th. City: <u>CH-1220</u> 20th. City: <u>CH-1220</u> 21st. City: <u>CH-1220</u> 22nd. City: <u>CH-1220</u> 23rd. City: <u>CH-1220</u> 24th. City: <u>CH-1220</u> 25th. City: <u>CH-1220</u> 26th. City: <u>CH-1220</u> 27th. City: <u>CH-1220</u> 28th. City: <u>CH-1220</u> 29th. City: <u>CH-1220</u> 30th. City: <u>CH-1220</u> 31st. City: <u>CH-1220</u> 32nd. City: <u>CH-1220</u> 33rd. City: <u>CH-1220</u> 34th. City: <u>CH-1220</u> 35th. City: <u>CH-1220</u> 36th. City: <u>CH-1220</u> 37th. City: <u>CH-1220</u> 38th. City: <u>CH-1220</u> 39th. City: <u>CH-1220</u> 40th. City: <u>CH-1220</u> 41st. City: <u>CH-1220</u> 42nd. City: <u>CH-1220</u> 43rd. City: <u>CH-1220</u> 44th. City: <u>CH-1220</u> 45th. City: <u>CH-1220</u> 46th. City: <u>CH-1220</u> 47th. City: <u>CH-1220</u> 48th. City: <u>CH-1220</u> 49th. City: <u>CH-1220</u> 50th. City: <u>CH-1220</u> 51st. City: <u>CH-1220</u> 52nd. City: <u>CH-1220</u> 53rd. City: <u>CH-1220</u> 54th. City: <u>CH-1220</u> 55th. City: <u>CH-1220</u> 56th. City: <u>CH-1220</u> 57th. City: <u>CH-1220</u> 58th. City: <u>CH-1220</u> 59th. City: <u>CH-1220</u> 60th. City: <u>CH-1220</u> 61st. City: <u>CH-1220</u> 62nd. City: <u>CH-1220</u> 63rd. City: <u>CH-1220</u> 64th. City: <u>CH-1220</u> 65th. City: <u>CH-1220</u> 66th. City: <u>CH-1220</u> 67th. City: <u>CH-1220</u> 68th. City: <u>CH-1220</u> 69th. City: <u>CH-1220</u> 70th. City: <u>CH-1220</u> 71st. City: <u>CH-1220</u> 72nd. City: <u>CH-1220</u> 73rd. City: <u>CH-1220</u> 74th. City: <u>CH-1220</u> 75th. City: <u>CH-1220</u> 76th. City: <u>CH-1220</u> 77th. City: <u>CH-1220</u> 78th. City: <u>CH-1220</u> 79th. City: <u>CH-1220</u> 80th. City: <u>CH-1220</u> 81st. City: <u>CH-1220</u> 82nd. City: <u>CH-1220</u> 83rd. City: <u>CH-1220</u> 84th. City: <u>CH-1220</u> 85th. City: <u>CH-1220</u> 86th. City: <u>CH-1220</u> 87th. City: <u>CH-1220</u> 88th. City: <u>CH-1220</u> 89th. City: <u>CH-1220</u> 90th. City: <u>CH-1220</u> 91st. City: <u>CH-1220</u> 92nd. City: <u>CH-1220</u> 93rd. City: <u>CH-1220</u> 94th. City: <u>CH-1220</u> 95th. City: <u>CH-1220</u> 96th. City: <u>CH-1220</u> 97th. City: <u>CH-1220</u> 98th. City: <u>CH-1220</u> 99th. City: <u>CH-1220</u> 100th. City: <u>CH-1220</u>		

SGS		
1st Floor	210, 220, 230, 240, 250, 260, 270, 280, 290, 300, 310, 320, 330, 340, 350, 360, 370, 380, 390, 400, 410, 420, 430, 440, 450, 460, 470, 480, 490, 500, 510, 520, 530, 540, 550, 560, 570, 580, 590, 600, 610, 620, 630, 640, 650, 660, 670, 680, 690, 700, 710, 720, 730, 740, 750, 760, 770, 780, 790, 800, 810, 820, 830, 840, 850, 860, 870, 880, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 990, 1000, 1010, 1020, 1030, 1040, 1050, 1060, 1070, 1080, 1090, 1100, 1110, 1120, 1130, 1140, 1150, 1160, 1170, 1180, 1190, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1270, 1280, 1290, 1300, 1310, 1320, 1330, 1340, 1350, 1360, 1370, 1380, 1390, 1400, 1410, 1420, 1430, 1440, 1450, 1460, 1470, 1480, 1490, 1500, 1510, 1520, 1530, 1540, 1550, 1560, 1570, 1580, 1590, 1600, 1610, 1620, 1630, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 1710, 1720, 1730, 1740, 1750, 1760, 1770, 1780, 1790, 1800, 1810, 1820, 1830, 1840, 1850, 1860, 1870, 1880, 1890, 1900, 1910, 1920, 1930, 1940, 1950, 1960, 1970, 1980, 1990, 2000, 2010, 2020, 2030, 2040, 2050, 2060, 2070, 2080, 2090, 2100, 2110, 2120, 2130, 2140, 2150, 2160, 2170, 2180, 2190, 2200, 2210, 2220, 2230, 2240, 2250, 2260, 2270, 2280, 2290, 2300, 2310, 2320, 2330, 2340, 2350, 2360, 2370, 2380, 2390, 2400, 2410, 2420, 2430, 2440, 2450, 2460, 2470, 2480, 2490, 2500, 2510, 2520, 2530, 2540, 2550, 2560, 2570, 2580, 2590, 2600, 2610, 2620, 2630, 2640, 2650, 2660, 2670, 2680, 2690, 2700, 2710, 2720, 2730, 2740, 2750, 2760, 2770, 2780, 2790, 2800, 2810, 2820, 2830, 2840, 2850, 2860, 2870, 2880, 2890, 2900, 2910, 2920, 2930, 2940, 2950, 2960, 2970, 2980, 2990, 3000, 3010, 3020, 3030, 3040, 3050, 3060, 3070, 3080, 3090, 3100, 3110, 3120, 3130, 3140, 3150, 3160, 3170, 3180, 3190, 3200, 3210, 3220, 3230, 3240, 3250, 3260, 3270, 3280, 3290, 3300, 3310, 3320, 3330, 3340, 3350, 3360, 3370, 3380, 3390, 3400, 3410, 3420, 3430, 3440, 3450, 3460, 3470, 3480, 3490, 3500, 3510, 3520, 3530, 3540, 3550, 3560, 3570, 3580, 3590, 3600, 3610, 3620, 3630, 3640, 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SGS

Free Member **\$1,000 (\$400 Refund)** **Start May 11, 2009** **Free 6 x 6 ft**

General Admission \$100 (\$40 Refund) Start May 11, 2009

Registration: International Solid Rocket Fuel, Atomic and Antimatter (2 x 2 ft)

Top Entry

Admission: \$100 (\$40 Refund) Start May 11, 2009

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产品FDA资质 FDA certification of product

医用防护服/隔离衣FDA列示 (FDA certification of Medical Protective Clothing and Isolation Gown)



U.S. Department of Health & Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products Veterinary, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Establishment Registration & Device Listing

FDA Home Medical Devices Devices

1 result found for Establishment Registration or Business Trade Name : Biossis Healing

Establishment Name	Registration Number	Current Registration Ex.
BIOSSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD. CHINA	30600401	2020
- Non-Surgical Isolation Gown, Isolation Gown, Medical Protective Clothing - Accessories, Isolation Gown, Isolation Gown, Isolation Gown, Isolation Gown - Face Mask, Closure, N95 Respirator For Patient, Patient Headdress Personal Protective Equipment, Medical Face Mask - Cover, Gown, Isolation Gown, Isolation Gown		

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U.S. Department of Health & Human Services
FDA U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products Veterinary, Blood & Biologics Animal & Veterinary

Establishment Registration & Device Listing

FDA Home Medical Devices Devices

1 result found for Establishment Registration or Business Trade Name : Biossis Healing

Proprietary Name:	Isolation Gown, Medical Protective Clothing
Classification Name:	NON-SURGICAL ISOLATION GOWN
Product Code:	324
Device Class:	I
Registration Number:	30600401
Regulatory Agency:	Isolation & Protection
Registered Establishment Name:	BIOSSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD.
Registered Establishment Number:	30600401
Owner/Operator:	Biossis Healing Biological Technology Co., Ltd.
Device Operator Number:	1000001
Establishment Operations:	Manufacturer

- * 相关信息可自如下网站确认: www.accessdata.fda.gov
- * All information can be double-checked from this official web: www.accessdata.fda.gov

• 专注再生医学 植入健康信赖 • Biossishealing Implant Trust

 BIOSIS HEALING
博辉瑞进[illegible][illegible]

组织结构调整。PPT 2000

企 业 名 称: 北京博晖光电技术股份有限公司

企业性质: 北京西人药厂中美生物科技园及神州生物医药
 医药研究所一司中美药厂(天津) 医药所

亦正知甘美則

来源登记日期: 2015-07-21 20:12

法定代理人: 姜明

有 幾 期: 102期

注意：海关：2017.12.14
核发日期：2017.12.14

• 专注再生医学 植入健康信赖 • Bioshealing Implant Trust

产品出口证明 Product export certification



中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

发证机关：国家药品监督管理局
Issuing Authority:
State Food and Drug Administration

产品名称：医用缝合线
Product Name: Medical Suture

注册证号：国械注准（2014）2030486
Registration Certificate No.: 国械注准（2014）2030486

生产企业：北京博辉瑞进医疗器械有限公司
Manufacturer: Beijing Bioscience Medical Technology Co., Ltd.

生产地址：北京市昌平区北七家镇未来科学城核心区二区二街二号楼二单元
Address of Manufacturer: 2020 North No. 2, Street No. 2, Building No. 2, Unit 2, Future Science City Core Area 2, Beiqiaojia Town, Changping District, Beijing, 102209, P.R. China

出口国（地区）名称：美国
Exporting Country (Area): USA

备注：本证书的有效性依赖于生产企业符合《医疗器械监督管理条例》的要求。
Remarks: This is for supply and use in accordance with the requirements of the Medical Device Regulation.

发证日期：2014年12月10日
Issuing Date: 2014-12-10

发证机关：国家药品监督管理局
Issuing Authority: State Food and Drug Administration



中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

发证机关：国家药品监督管理局
Issuing Authority:
State Food and Drug Administration

产品名称：医用缝合线
Product Name: Medical Suture

注册证号：国械注准（2014）2030486
Registration Certificate No.: 国械注准（2014）2030486

生产企业：北京博辉瑞进医疗器械有限公司
Manufacturer: Beijing Bioscience Medical Technology Co., Ltd.

生产地址：北京市昌平区北七家镇未来科学城核心区二区二街二号楼二单元
Address of Manufacturer: 2020 North No. 2, Street No. 2, Building No. 2, Unit 2, Future Science City Core Area 2, Beiqiaojia Town, Changping District, Beijing, 102209, P.R. China

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Thank you



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网址: www.biosishealing.com

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