

**K203821 Donagamex Blue Performance Protective Gown**Dec 17, 2021  
353 days to decisionK203821 · Product code: **QPC** · General Hospital  
Source: <https://www.510kdatabase.net/k203821/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Non-sterile, Non-isolation, Intended To Provide Moderate Or High Barrier Protection (QPC)
Date received	Dec 29, 2020
Decision date	Dec 17, 2021
Days to decision	353 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dong Nai Garment Corporation (Donagamex)</b>
Location	Bien Hoa City, VN
Contact	Bui The Kich
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mdi Consultants, Inc.</b>
Contact	Bari Steinberg

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203821/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 26, 2026