



Tailwind for International Markets

Daedalus[®]
by RegIntA[®]

Looking for New Markets?

Each country has different regulatory approval requirements. This presents challenges and opportunities.

With our Daedalus® database we support you in launching your devices faster and more successfully to the international market.

New Perspectives in Internationalisation

This includes not only economic, political, social or cultural aspects - you also need to be familiar with the current regulatory approval procedures.

Internationalisation is an important step for the long-term success of your company.

To survive in international competition, it is necessary to have a precise knowledge of the markets of the countries to which you want to export.

Knowledge Advantage

We want to provide you with the knowledge needed to make **strategic decisions and negotiate on equal terms with distributors and importers.**

This enables you to **bring your devices successfully and faster to the respective market and save time and costs.**

While your **products are still in development**, you already **benefit from access to the regulatory requirements for your target markets** in order to have all **required clinical evaluations** ready when the time comes.

bvmed.de | Kurt Paulus

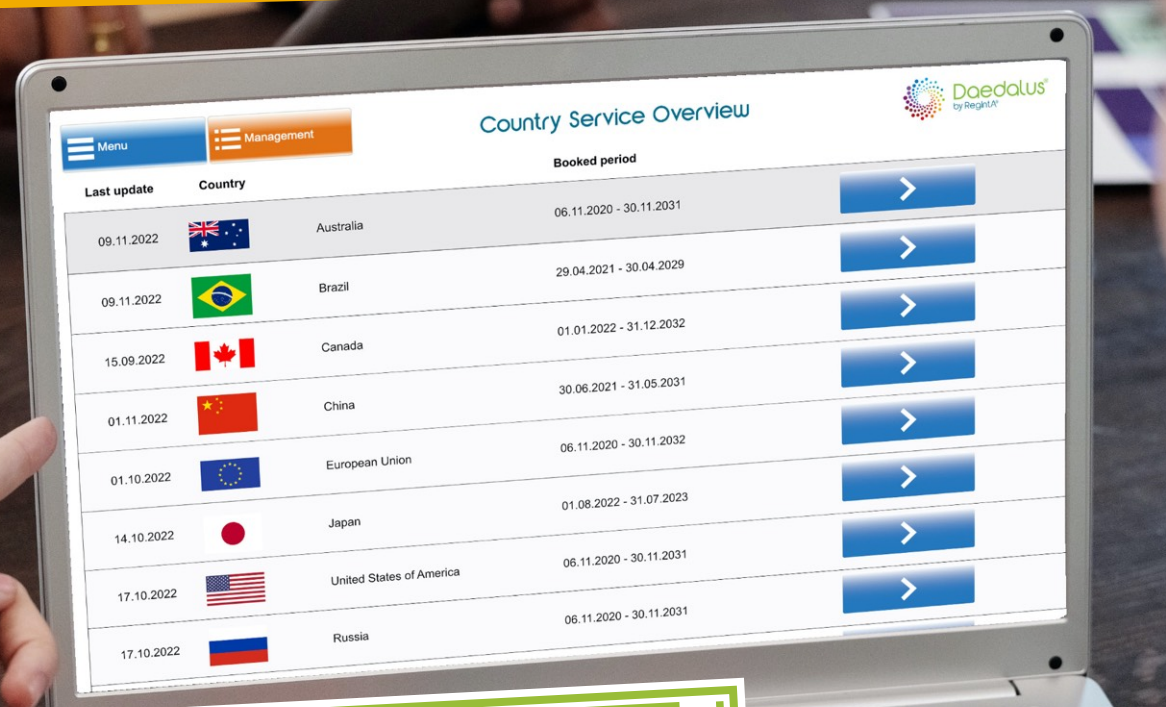
Relief Your Department









Do not waste resources on time-consuming research on legislation and ensure that your team can focus on their core competences.

We support you in this with our online database Daedalus®, which provides you with global up-to-date regulatory intelligence on the entire life cycle of medical devices.

Select the Countries Relevant for You...

Legal Certainty



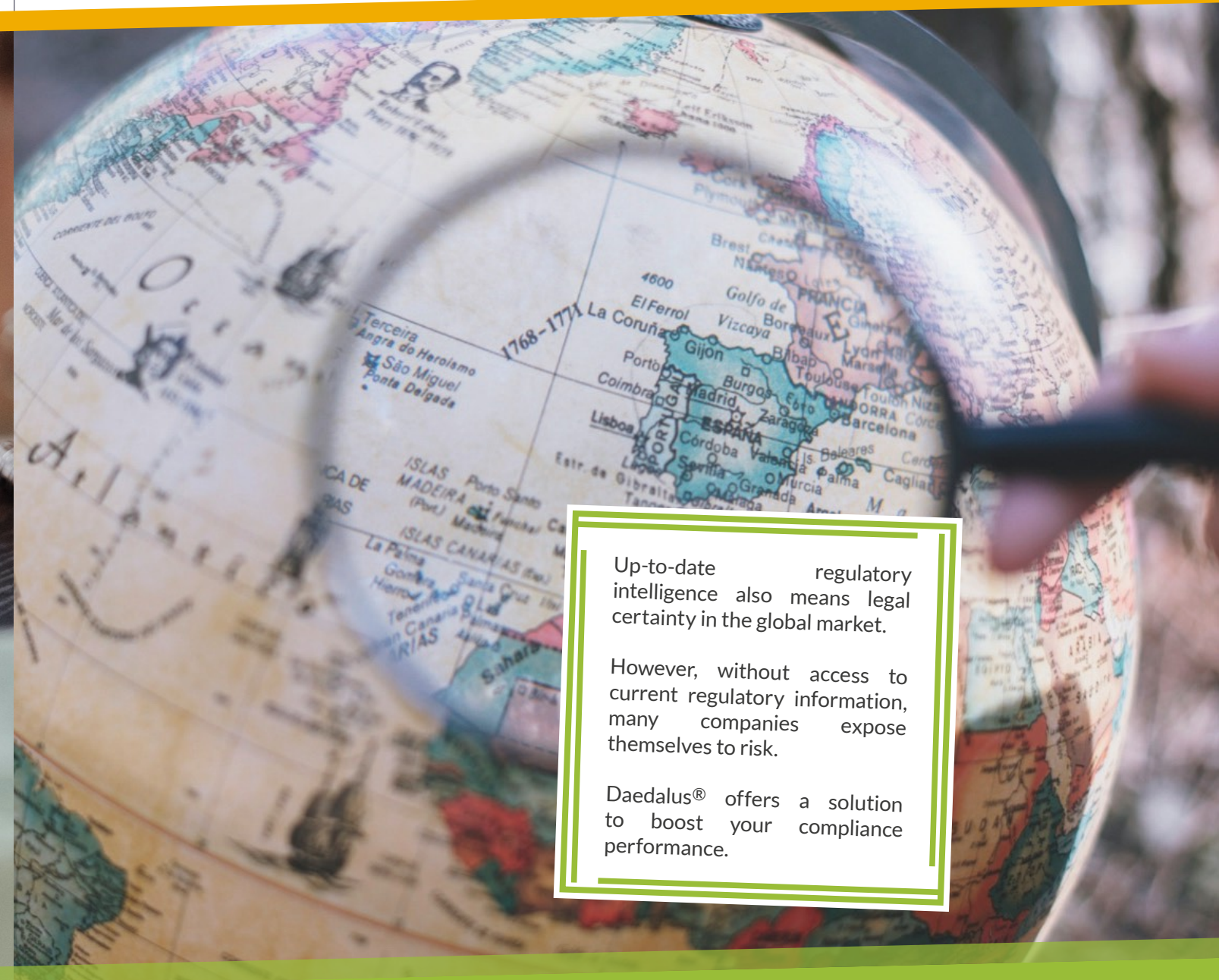
| Last update | Country | Booked period | |
|-------------|--|-------------------------|---|
| 09.11.2022 |  Australia | 06.11.2020 - 30.11.2031 | > |
| 09.11.2022 |  Brazil | 29.04.2021 - 30.04.2029 | > |
| 15.09.2022 |  Canada | 01.01.2022 - 31.12.2032 | > |
| 01.11.2022 |  China | 30.06.2021 - 31.05.2031 | > |
| 01.10.2022 |  European Union | 06.11.2020 - 30.11.2032 | > |
| 14.10.2022 |  Japan | 01.08.2022 - 31.07.2023 | > |
| 17.10.2022 |  United States of America | 06.11.2020 - 30.11.2031 | > |
| 17.10.2022 |  Russia | 06.11.2020 - 30.11.2031 | > |

...and ensure your **regulatory compliance**.

We cover the most important markets such as the **USA, Canada, China, Japan, Brazil, the EU and Australia**. But you will also find many smaller markets in Daedalus®.

We will be happy to work out the relevant legal requirements for further markets on your behalf.

Please contact us.



Up-to-date regulatory intelligence also means legal certainty in the global market.

However, without access to current regulatory information, many companies expose themselves to risk.

Daedalus® offers a solution to boost your compliance performance.

Life-Cycle

Up-to-Date Information



All data is regularly checked in accordance with our Quality Management System.

Changes are promptly incorporated into the database to ensure that you are always up to date.



New or changed sources with impact on regulatory intelligence



The RegIntA team updates the regulatory intelligence and performs a quality check.

A new version with version history is uploaded for the client.

Daedalus®

The RegIntA team checks the available data in Daedalus® to ensure it is up-to-date.

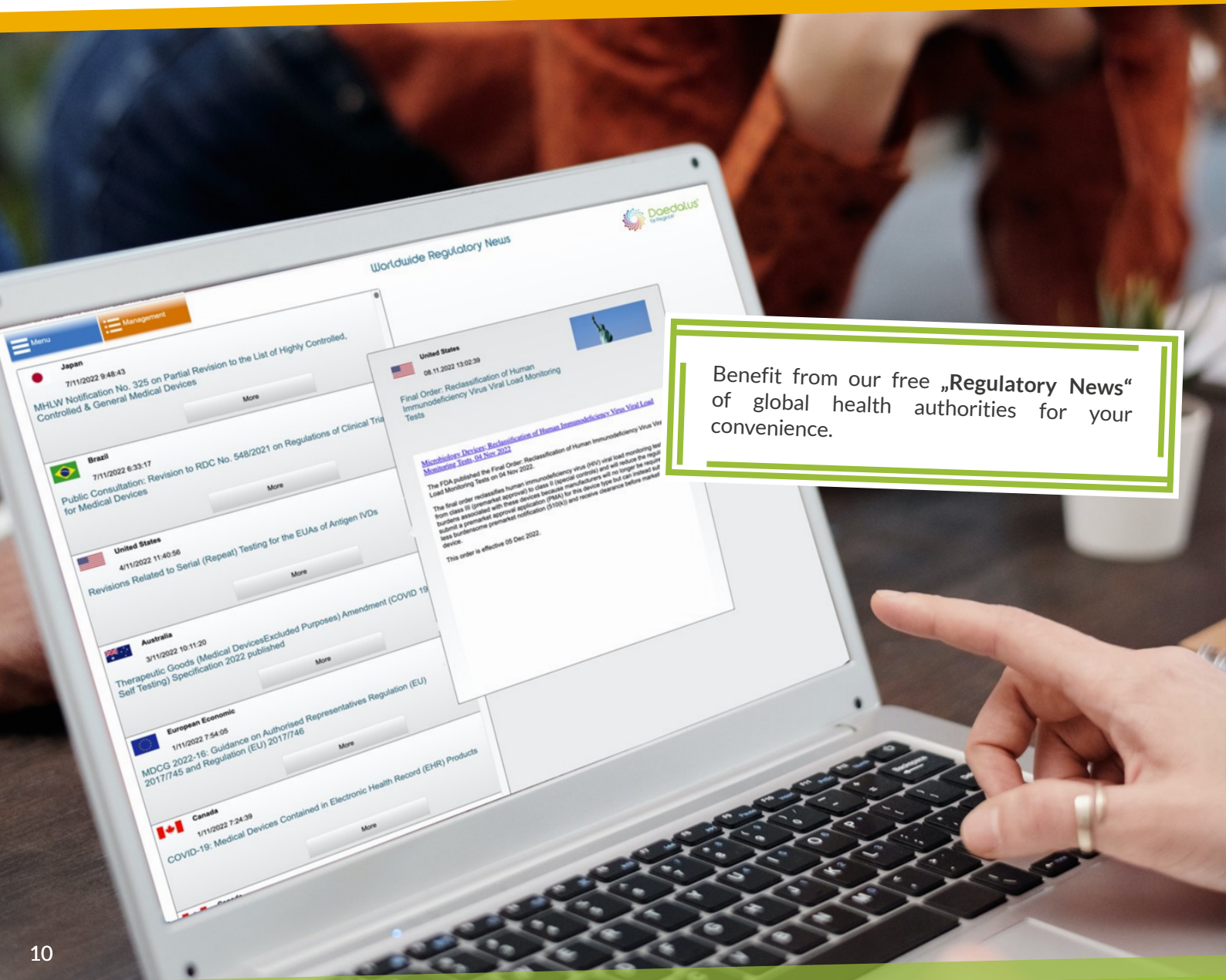
The client has access to up-to-date regulatory intelligence



The regulatory intelligence we offer in Daedalus® goes beyond the compilation of documents required for the **product registration**. Instead, it covers the **entire life cycle** of your medical device.

This includes information about change notifications, registration renewal as well as vigilance & PMS requirements.

Regulatory News Inclusive



Benefit from our free „Regulatory News“ of global health authorities for your convenience.

Client Management



Online booking and overview of

- ◆ Countries
- ◆ Accounts
- ◆ Invoices
- ◆ Orders

Get in touch with us.
We look forward speaking to you.

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Subject to change. 4.0



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FOR YOUR COMPLIANCE

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