Becton, Dickinson and Company
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VIA EDGAR

March 28, 2022

Mr. Michael Fay
Mr. Brian Cascio
Division of Corporation Finance
Office of Life Sciences
U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

Re: Becton, Dickinson and Company
Form 10-K for the Year Ended September 30, 2021
Filed November 24, 2021
Form 8-K
Filed November 4, 2021
File No. 001-04802

Dear Mr. Fay and Mr. Cascio:

Becton, Dickinson and Company (the "Company" or "we," "our," or "us") is writing this letter in response to the comment letter of the Staff of the Securities and Exchange Commission (the "Staff" of the "Commission") dated March 2, 2022, relating to the Company's Form 10-K for the year ended September 30, 2021 (the "Form 10-K") and the Company's Form 8-K filed on November 4, 2021.

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For your convenience, we have reproduced the Staff's comment preceding our response below. Please let us know if you have any questions or if we can provide additional information or otherwise be of assistance in expediting the review process.

Form 8-K Filed November 4, 2021
Exhibit 99.1
Reconciliation of Reported Diluted EPS to Adjusted Diluted EPS, page 12

1. We note your non-GAAP measure Adjusted Diluted EPS includes an adjustment for "costs required to develop processes and systems to comply with regulations such as the EU MDR and GDPR." Please tell us why you believe the adjustment for these costs is consistent with the guidance in Question 100.01 of the Non-GAAP Financial Measures Compliance and Disclosure Interpretations given that costs to comply with regulations, whether new, old, or revised, appear to be "normal, recurring, cash operating expenses necessary to operate [your] business." As part of your response, provide us a detailed description of these costs, organized by regulation and type of cost and project, for each of the periods presented in your most recent Form 10-K and subsequent Form 10-Q. Include quantification of the expenses.

Response:

In response to the Staff's comment, we acknowledge Question 100.01 of the Non-GAAP Compliance and Disclosure Interpretations (the "C&DIs"), as well as Rule 100(b) of Regulation G to which such Question relates. Question 100.01 states that certain adjustments, while not explicitly prohibited, could cause the presentation of non-GAAP financial information to be misleading. We also note that Question 102.03 of the C&DIs provides that "[t]he fact that a registrant cannot describe a charge or gain as nonrecurring, infrequent or unusual, however, does not mean that the registrant cannot adjust for that charge or gain. Registrants can make adjustments they believe are appropriate, subject to Regulation G and the other requirements of Item 10(e) of Regulation S-K."

We respectfully advise the Staff that we have considered the prescribed guidance and the Staff's overall perspective regarding non-GAAP measures, and we believe that the exclusion of the European regulatory initiative-related costs (the "European Regulatory Costs") from our calculation of Adjusted Diluted Earnings per Share ("Adjusted Diluted EPS") does not cause this non-GAAP financial measure to be misleading.

Regulatory background

Our operations are global and are affected by complex state, federal and international laws relating to healthcare, environmental protection, antitrust, anti-corruption, marketing, fraud and abuse (including anti-kickback and false claims laws), export control, product safety and efficacy, employment, privacy and other areas. Our products are subject to regulation in over 90 countries and we continuously monitor and assess the potential impact of any new or amended regulation on our business. Over the past year, we have identified and analyzed 88 new or amended regulations relating to our products, with 35 additional relevant legislative proposals not yet adopted. Consequently, we incur significant expenses in each fiscal period to ensure our ongoing compliance with applicable laws and regulations.

We do not exclude from our non-GAAP financial measures, including our Adjusted Diluted EPS, ordinary, recurring legal and compliance costs that are related to our ongoing day-to-day operations, including costs incurred in connection with complying with ordinary course changes in regulatory schemes applicable to us that arise from time-to-time. However, the European Union Medical Device Regulation (the "EU MDR") and the similar In Vitro Diagnostic Medical Device Regulation (the "EU IVDR," and together with the EU MDR, the "New EU Medical Devices Regulations"), and the General Data Protection Regulations (the "GDPR") each represented a significant, unprecedented change to an existing European regulatory framework and, as such, are clearly distinguishable from ordinary course changes and regulatory developments. In particular, as discussed in more detail below, these expansive and transformative regulations require substantial, one-off changes to our systems and processes, and, in the case of the New EU Medical Devices Regulations, the incurrence of one-off and duplicative certification and registration expenses for a significant portfolio of our medical products that are already approved for sale in the EU under the current regulatory framework.

The European Regulatory Costs that we exclude from Adjusted Diluted EPS are solely upfront expenses that are directly attributable to establishing initial compliance with these new regulations and, as such, are limited both in scope and time given the transition periods provided for in the New EU Medical Devices Regulations and the GDPR. Therefore, we respectfully submit these costs are unusual and non-recurring, and are not representative of the underlying operating performance of our business. Accordingly, we believe excluding these costs from our Adjusted Diluted EPS is appropriate in these specific circumstances and is consistent with Question 100.01 of the C&DIs.

In response to the Staff's comment, we discuss the adjustment with respect to each of the New EU Medical Devices Regulations and the GDPR projects separately below. We discuss the New EU Medical Devices Regulations together because of the similarities between the regulatory requirements both the EU MDR and the EU IVDR impose and the overlapping compliance efforts and resources needed to achieve compliance with these regulations. This approach is also consistent with how we presented these excluded costs in our historical public filings where we referred to both the EU MDR and the EU IVDR collectively as the "EU MDR."

New EU Medical Devices Regulations

The EU MDR, adopted by the EU in 2017, replaces the EU Medical Devices Directive (the "EU MDD"), which, together with the EU In Vitro Diagnostic Medical Devices Directive (the "EU IVDD"), has been the legislation applicable to our medical products sold in the EU since the 1990s. The New EU Medical Devices Regulations impose wide-ranging changes affecting the marketing and sale of medical devices and *in vitro* devices ("IVDs"), including the area of clinical evaluation requirements, quality systems, economic operators and post-market surveillance. The new, heightened requirements under the New EU Medical Devices Regulations apply not only to new products, but also to products previously approved under the EU MDD and EU IVDD, as applicable. Effective May 2021, manufacturers of medical devices already approved must meet the new requirements of the EU MDR for self-certified devices and have until May 2024 to meet the requirements for medical devices with a valid conformity assessment certificate. Similarly, under the EU IVDR, manufacturers have until May 2022 to meet the new requirements for self-certified IVDs and up to May 2027 for IVDs that require a conformity assessment certificate, including for existing products already approved under the EU IVDD.

As a result, we are required to achieve compliance under the New EU Medical Devices Regulations for all products previously approved under the existing EU framework to continue to manufacture, market or sell them in the EU. Unlike many similar regulations governing the manufacturing, marketing and sale of medical devices, the New EU Medical Devices Regulations do not allow the grandfathering of existing and already-approved products. To illustrate the wide-ranging scope of these regulations, we note that we are required to analyze over 500 technical documentation files related to more than 7,000 of our medical products already approved under the existing EU framework in connection with registration or self-certification of such products under the New EU Medical Devices Regulations. Notably, with respect to many of our self-certified IVDs under the EU IVDD, we are now required to undergo a more costly and complex assessment and review process under the EU IVDR. Further, in preparation of mandatory regulatory submissions under the New EU Medical Devices Regulations, we are required to conduct new clinical trials for many of

our medical devices already approved under the existing EU framework. Consequently, the associated costs are one-off and duplicative of the costs that we already incurred while registering or self-certifying such products under the prior EU directives and arise solely because of this unprecedented overhaul of the EU regulatory framework.

In addition, we are also implementing significant one-time changes to our manufacturing and support processes and systems, including updating all existing labelling materials and developing enhanced post-market surveillance processes and systems to meet new requirements under the New EU Medical Devices Regulations. These changes are distinguishable from ordinary course system and process updates because of the expansive scope and fundamental nature of the changes required to establish initial compliance with these regulations.

The European Regulatory Costs relating to the New EU Medical Devices Regulations that we exclude from our Adjusted Diluted EPS are solely one-time costs relating to previously approved products and changes to our manufacturing and support processes and systems, as described above. These costs can be categorized by type as follows:

- Project Labor – These costs include salary, benefits and contract expenses related to specified internal personnel and third-party professionals, in each case whose roles are dedicated solely to carrying out activities described above related to establishing initial compliance with the New EU Medical Devices Regulations as well as ancillary activities. In the case of internal personnel, these are dedicated employees that have been reassigned within the Company or employed to work exclusively on activities described above. For employees that have been reassigned internally to work on the New EU Medical Devices Regulations, in many instances we also added new personnel to fill the prior roles of those employees that were reassigned to work exclusively on this project. We do not exclude the incremental costs from these new personnel from our Adjusted EPS. Following completion of the initial compliance work for the New EU Medical Devices Regulations, we generally do not expect to keep the related positions.

- Outside Services and Consulting – These costs include external research and development and clinical trial expenses for our medical products that are already approved under the existing regulatory framework in the EU. These costs also include consulting, legal and other fees paid to external partners for performing various one-time activities related to establishing initial compliance with the New EU Medical Devices Regulations.
- Supplies, Travel and Other – These costs include supplies costs, including scrap expenses and manufacturing variance adjustments, travel and other miscellaneous costs incurred in

connection with the activities described above related to establishing initial compliance with the New EU Medical Devices Regulations, as well as ancillary activities.

In response to the Staff's comment, we have provided below a summary of these costs for this project, organized by type of cost for each of the periods presented in our most recent Form 10-K and subsequent Form 10-Q.

Type of Cost	**Fiscal Quarter Ended December 31,**		**Fiscal Year Ended September 30,**		
($ in millions)	**2021**	**2020**	**2021**	**2020**	**2019**
Project Labor	$17	$16	$64	$47	$22
Outside Services and Consulting	12	9	63	37	18
Supplies, Travel and Other	2	1	9	20	9
Total	**$31**	**$26**	**$135**	**$104**	**$49**

Note: Totals may not add due to rounding.

While these costs have been excluded from our Adjusted Diluted EPS beginning in our fiscal year ended September 30, 2019, we will incur them only for a discrete transition period. In particular, while we expect to continue to incur material European Regulatory Costs during our current fiscal year ending September 30, 2022 as well as our fiscal years ending September 30, 2023 and 2024, we also expect such excluded costs to steadily and sharply decline in each of these fiscal years. We also advise the Staff that, while the EU IVDR provides for a transition period up until May 2027 for certain IVDs, we expect to substantially complete our efforts to establish initial compliance during the transition period for the EU MDR. Consequently, absent changes to the New EU Medical Devices Regulations, we do not anticipate making adjustments to our Adjusted EPS measure for these regulations following our fiscal year ending September 30, 2024. Finally, as mentioned above, significant changes to such regulations are not common, as we have been operating under the EU MDD and the EU IVDD since the 1990s, which further underscores the unusual nature of the excluded costs and the fact that they are not representative of our underlying operating performance.

GDPR

The collection, use, disclosure, transfer or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which became effective in May 2018. The GDPR is wide-ranging in scope and imposes multiple onerous requirements on companies that process personal data. As a result, to establish initial compliance with the GDPR, we engaged third parties to implement one-time changes to our systems, policies and procedures in order to enhance privacy protections in line with the GDPR requirements, create new tools to maintain GDPR-compliant data inventories and develop new internal policies and procedures to comply with the new data privacy regime.

In response to the Staff's comment, we have provided below a summary of these costs for this project, organized by type of cost for each of the periods presented in our most recent Form 10-K and subsequent Form 10-Q. As shown below, these costs solely included consulting, legal and other fees paid to external consulting partners for performing various one-time activities related to establishing initial compliance with the GDPR.

Type of Cost	**Fiscal Quarter Ended December 31,**		**Fiscal Year Ended September 30,**		
($ in millions)	**2021**	**2020**	**2021**	**2020**	**2019**
Outside Services and Consulting	—	—	—	$2	$2
Total	**—**	**—**	**—**	**$2**	**$2**

Each of the activities described above, and therefore the related costs that we exclude from our Adjusted Diluted EPS measure, are directly attributable to establishing initial compliance with the GDPR. All such activities and related costs were limited in time and scope. Specifically, our initial compliance efforts were substantially completed in our fiscal year 2020. As a result, no costs directly attributable to establishing initial compliance with the GDPR have been incurred, and no related adjustment has been made, for any periods subsequent to our fiscal year ended September 30, 2020. Similarly, we do not anticipate making such adjustments in any future periods.

Conclusion

For the reasons set forth above, we respectfully submit that the European Regulatory Costs excluded from our Adjusted Diluted EPS measure, which are solely upfront expenses directly attributable to establishing initial compliance with these regulations, are unusual and non-recurring expenses that are limited in time and scope and are not representative of our

underlying operating performance. As a result, we do not consider such expenses normal, recurring, ordinary course expenditures.

Such expenses are also excluded from performance measures our management uses to evaluate our operating performance, to analyze trends within our business, to assess our performance relative to our competitors, and to establish operational goals and forecasts that are used in allocating resources. Consequently, we believe that the adjustment to our Adjusted Diluted EPS to exclude these European Regulatory Costs helps investors measure our core operating performance and better understand our financial results on the same consistent basis from period to period in line with the methodology utilized by our management.

We also are aware of other large multinational medical technology companies that similarly make comparable adjustments to their non-GAAP measures related to costs relating to establishing initial compliance with the New EU Medical Devices Regulations. As a result, we believe that the adjustment to our Adjusted Diluted EPS to exclude these European Regulatory Costs can help investors compare our operating performance to the operating performance of other companies in our industry that also exclude these costs. Thus, we respectfully submit that the exclusion of the European Regulatory Costs from our calculation of Adjusted Diluted EPS as disclosed in our public filings is not misleading and provides the requisite level of transparency into the methodology used by management to evaluate and measure operating performance.

In order to further enhance our disclosures in future filings, we hereby advise the Staff that in future filings we will expand our disclosure regarding the use of non-GAAP measures and related adjustments to include disclosure similar to the underlined text in the extract below. We believe that this expanded disclosure will help investors better understand the specific nature of the costs, the time horizon of such costs and our view that these costs are not normal, recurring, cash operating expenses.

> Current and prior-year adjusted diluted earnings per share results exclude, among other things, the impact of purchase accounting adjustments, integration and restructuring costs, spin-off related charges, certain transaction gains and losses, certain legal defense and product remediation costs, certain regulatory costs, certain investment gains and losses, the impact of the extinguishment of debt and the dilutive impact of outstanding preferred stock. In particular, current and prior-year adjusted diluted earnings per share results exclude European regulatory initiative-related costs, which represent costs incurred to develop processes and systems to establish initial compliance with the European Union Medical Device

Regulation and the European Union In Vitro Diagnostic Medical Device Regulation (collectively, the "New EU Medical Devices Regulations"), which represent a significant, unusual change to the existing regulatory framework. We consider the excluded European regulatory initiative-related costs to be duplicative of previously incurred costs and/or one-off costs related to establishing initial compliance with such regulatory regimes, and in each case are limited to a specific period of time. These expenses relate to establishing initial compliance with the New EU Medical Devices Regulations and include the cost of labor, other services and consulting (in particular, research and development and clinical trials) and supplies, travel and other miscellaneous costs. These costs were recorded in *Cost of products sold* and *Research and development expense*.

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In connection with our response to the Staff's comment, we acknowledge that the Company and our management are responsible for the accuracy and adequacy of our disclosures, notwithstanding any review, comments, action or absence of action by the Staff.

Please do not hesitate to call me at (201) 847-6314 with any questions you may have with respect to the foregoing.

Very truly yours,

BECTON, DICKINSON AND COMPANY

By: /s/ Thomas J. Spoerel
Name: Thomas J. Spoerel
Title: Senior Vice President,
Controller & Chief Accounting Officer

cc: Christopher J. DelOrefice, Executive Vice President and Chief Financial Officer
Samrat S. Khichi, Executive Vice President, Corporate Development, Public Policy, Regulatory Affairs and General Counsel
Gary DeFazio, Senior Vice President and Corporate Secretary