



EUROPEAN COMMISSION

DG Competition

*Case M.8523 – BD / Bard*

Only the English text is available and authentic.

**REGULATION (EC) No 139/2004**

**MERGER PROCEDURE**

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Decision on the implementation of remedies - Art. 6(1)(b)  
in conjunction with 6(2) - Purchaser approval

Date: 12.12.2017



## EUROPEAN COMMISSION

In the published version of this decision, some information has been omitted pursuant to Article 17(2) of Council Regulation (EC) No 139/2004 concerning non-disclosure of business secrets and other confidential information. The omissions are shown thus [...]. Where possible the information omitted has been replaced by ranges of figures or a general description.

Brussels, 12.12.2017  
C(2017) 8773 final

PUBLIC VERSION

To the notifying party:

Dear Sir/Madam,

**Subject: Case M.8523 – BD / Bard**  
**Approval of Merit Medical as purchaser of the Divestment Business following your letter of 16 November 2017 and the Trustee's opinion of 1 December 2017.**

### I. FACTS AND PROCEDURE

1. By decision of 18 October 2017 ("the Decision") based on Article 6(1)(b) in connection with Article 6(2) of Council Regulation (EC) No 139/2004<sup>1</sup>, the Commission declared the operation by which Becton, Dickinson and Company ("BD" or the "Notifying Party", US) acquires full control of C. R. Bard, Inc. ("Bard", US) compatible with the internal market following modification by the Notifying Party, subject to conditions and obligations (the "Commitments"). Bard and BD together are referred to as "the Parties".
2. In particular, the Commitments provide that BD divests the entirety of its global Core Needle Biopsy (CNB) product line and required production assets as well as two pipeline projects related to an innovative type of biopsy device ([name]) and a new type of tissue marker (Project [name]) (the "Divestment Business").
3. By letter of 16 November 2017, the Notifying Party proposed Merit Medical Systems, Inc. ("Merit", US) for approval by the Commission as purchaser of

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<sup>1</sup> OJ L 24, 29.1.2004, p. 1 (the "Merger Regulation").

the Divestment Business.<sup>2</sup> Merit is active in manufacturing of medical devices used in diagnostics and interventional cardiology and radiology procedures. It is headquartered in the US and operates manufacturing facilities in North America, Europe and the Pacific Rim. It also operates a global distribution network.

4. The Notifying Party submitted to the Commission the proposed Transaction Agreements, consisting of the Asset Purchase Agreement ("APA") and the Disclosure Schedule; the Transitional Services Agreement ("TSA"), and related schedules, the Contract Manufacturing Agreement ("CMA") and related schedules, the Distribution Agreement and related schedules; the Patent and Know-how License Agreement, the Patent Assignment Agreement, the Trademark Assignment Agreement, and the General Assignment and Bill of Sale (together referred to as the "Proposed Agreements") dated 15 November 2017.
5. Mazars LLP acting as Monitoring Trustee (the "Trustee") has provided an assessment of the Proposed Agreements and suggested several amendments to previous drafts that have been included by the Parties in the final version. The Commission has reviewed the Proposed Agreements and suggested a clarification of the definitions in the APA relating to confidential know-how and additional information related to the Product Lines and the pipeline projects to be divested. The Parties have agreed to clarify the correct interpretation of the respective parts of the Agreements in a confirmation letter of 1 December 2017. In his Reasoned Opinion of 1 December 2017, the Trustee comes to the conclusion that the Proposed Agreements fulfil the conditions set out in the Decision and that the confirmation letter of 1 December 2017 ensures that the Agreements are interpreted in line with the Commitments. In particular, the Trustee considers that:
  - a. Merit fulfils the Purchaser Requirements as set out in paragraph 17 of the Commitments and there are no indications that the Divestment Business would not be viable after the sale; and
  - b. the Divestment Business would be sold in a manner consistent with the Commitments.

## **II. ASSESSMENT OF THE PROPOSAL**

6. According to paragraph 18 of the Commitments, in its assessment of the Proposed Agreements, the Commission shall verify that the purchaser fulfils the Purchaser Criteria and that the Divestment Business is being sold in a manner consistent with the Commitments including their objective to bring about a lasting structural change in the market.

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<sup>2</sup> Merit agreed to pay USD [...] (adjusted for potential fluctuations in inventory) in cash for the Divestment Business, including the CNB biopsy devices business, the pipelines projects and the home drainage catheters business (the latest not being relevant for the purposes of this Decision as there are no overlaps between the activities of the parties in the EEA).

## II.1 Assessment of the purchaser criteria

7. As set out in recital (144) of the Decision and paragraph 17 of the Commitments, the purchaser of the Divestment Business must fulfil the following criteria:
  - a. be independent of and unconnected to the Parties and their Affiliated Undertakings;
  - b. have the financial resources, proven expertise in interventional radiology, R&D, manufacturing, marketing and sales, regulatory, logistics, and finance / IT administration capabilities and incentive to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors. In particular, after Closing the purchaser must have the capability, either directly or through third parties to cover at least 80% of BD's current sales in the EEA and to sterilize its CNB products;
  - c. neither be likely to create, in light of the information available to the Commission, *prima facie* competition concerns.
8. The Commission considers that Merit fulfils these criteria.

### (a) Independence from the Parties

9. Merit is a publically listed company and is neither owned nor controlled by the Parties or any of their affiliates.<sup>3</sup> No director of any of the Parties serves on the board of Merit or any of its affiliates and *vice versa*.<sup>4</sup> BD, Bard and Merit do not participate in any Joint Venture together and there do not appear to be entities in which they both hold a material interest.<sup>5</sup>
10. Only limited sales relations exist between the Parties and Merit. In total, BD purchased goods from Merit for USD [...] in 2016. Bard purchased goods from Merit for less than USD [...] and Merit's total purchases from BD were below USD [...] and from Bard below USD [...]. In light of Merit's total sales of more than USD 600 million, these purchases amount to less than [...]% of the purchaser's revenues and even significantly less of total turnover of the merged entity.<sup>6</sup> The Trustee has reviewed the commercial relations between the Parties and Merit and has concluded that the commercial links are immaterial for Merit and do not create a commercial dependency.
11. The Parties and Merit have common shareholders that hold more than 5% of their respective total outstanding shares, namely BlackRock Fund Advisors<sup>7</sup> and the Vanguard Group, Inc.<sup>8</sup> However, these shareholdings do not confer

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<sup>3</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 4.1.3.

<sup>4</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 4.3.

<sup>5</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 4.2.

<sup>6</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 4.4.

<sup>7</sup> BlackRock Fund Advisors hold ~[8]% of the total shares of BD, ~[10]% of the total share of BARD and ~[13]% of the total shares of Merit.

<sup>8</sup> The Vanguard Group, Inc hold ~[8]% of the total shares of BD, ~[11]% of the total share of BARD and ~[7]% of the total shares of Merit.

special rights and do not constitute a situation of control within the meaning of Article 3 of the Merger Regulation. Therefore, and for the purpose of this decision, the Commission does not conclude that these shareholdings impede the independence of Merit.

12. In light of the above, the Commission concludes that Merit fulfils the purchaser criterion of being independent of and unconnected to the Parties and their affiliated undertakings.

**(b) Financial resources, proven expertise, capability to cover at least 80% of BD's current sales and incentive to maintain and develop the Divested Business as a viable and active competitor**

*Financial resources*

13. Merit will finance the acquisition of the Divestment Business through its own cash reserves and existing credit facilities. It does not require and has not entered into new debt financing facilities for the fulfilment of the Proposed Agreements. Merit will acquire the Divestment Business for approx. USD [...], which is relatively small in comparison to its current market capitalisation of approximately USD [...].

14. The Trustee has reviewed the financing plans of Merit and has concluded that Merit has sufficient financial resources to acquire and develop the Divestment Business, taking into account that the acquisition is a relatively small transaction in relation to the overall size and market capitalisation of Merit.

15. Taking into account the financial situation of Merit and considering the size of the acquisition in relation to Merit's revenues and market capitalisation, the Commission concludes that Merit fulfils the criterion of having the financial resources to maintain and develop the Divestment Business as a viable and active competitive force in competition with the Parties and other competitors.

*Proven expertise*

16. Merit has experience in the design, development, manufacturing and marketing of medical devices since its foundation and has been active in the area for 30 years. It employs over 4 700 employees in 17 countries and sells its products in over 120 countries either directly or via distributors. It has the relevant administrative and IT structures in place, including marketing and sales, logistics, regulatory, and finance to operate its current business.<sup>9</sup>

17. Merit has proven its ability to develop, manufacture and commercialise a range of medical devices sold to interventional radiologists such as introducers, dilators, needles, dialysis products, diagnostic guidewires, diagnostic peripheral catheters, fluid management, balloon catheters, inflation devices, snares, drainage catheters, or support catheters. Merit manufactures a number of

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<sup>9</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.1.

components which are used in the assembly of CNB devices and therefore has the necessary moulding and extrusion expertise and capabilities.<sup>10</sup>

18. In addition, Merit has developed a full core automatic soft tissue device "CorVocet" that was introduced on the US market in 2016 and will be broadly available in the EEA in [...].<sup>11</sup> Merit's internal division that is responsible for this new product has additional relevant experience given its activities in other areas of interventional radiology like access devices (introducers and needles), and devices for angiographic diagnostics and intervention (diagnostic peripheral catheters, guidewires and syringes, balloon catheters and inflation devices).<sup>12</sup>
19. Merit is also active in bone biopsy following its acquisition of the assets of Laurane Medical in August 2017.<sup>13</sup> The Trustee reviewed the acquisition of the associated product offerings, additional accessories and customer base and came to the conclusion that Merit may build upon this base to further develop sales in adjacent biopsy markets.
20. The Divestment Business would complement Merit's existing business with adjacent products that feature some similarities from a production perspective. In particular, Merit operates its own manufacturing equipment including injection moulding, laser cutting, extrusion and braiding.<sup>14</sup> Merit would acquire [...] manufacturing equipment and machinery from BD that is used for the production of the CNB product lines. The production lines would be transferred to Merit's manufacturing facility in [place] that has sufficient space as well as access to work force that Merit believes can be trained within a reasonable time to operate the equipment to be acquired. Currently, the [place] facility operates at only [...]% capacity.<sup>15</sup>
21. Merit has manufacturing transfer experience and has transferred successfully [...] product lines to its facility in [place].<sup>16</sup> In addition, it has accomplished several acquisitions, including carve-outs of manufacturing facilities that were integrated into their own production facilities.<sup>17</sup> Merit therefore expects to be able to complete the transfer period within approximately 6 months, and in no event more than 12 months.<sup>18</sup>
22. As regards sterilisation capabilities for CNB products, BD outsourced the sterilization process of CNB devices to third party suppliers. Merit also contracts sterilization services using outside suppliers, having qualified back up suppliers for all sites.<sup>19</sup>

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<sup>10</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.1.

<sup>11</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 7.1.

<sup>12</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.1.

<sup>13</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.1.3.1.

<sup>14</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.1.2.

<sup>15</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.2.2 and 6.2.3.

<sup>16</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.2.4.

<sup>17</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 1.3.2.

<sup>18</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.2.2.

<sup>19</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.1.5.

23. Upon transfer of the Divestment Business to Merit's production facility in [place], sterilisation is intended to be provided by the current suppliers of Merit located in the US. Merit confirms that qualified back-up suppliers for all of its manufacturing sites exists and that it monitors capacity at each supplier on a quarterly basis. Therefore, Merit would be in a comparable position as BD with regard to the sterilization process.<sup>20</sup>
24. Merit further has a track record of developing and introducing new products on the market.<sup>21</sup> Merit employs more than [...] R&D personnel at 9 locations worldwide, including 3 locations within the EEA.<sup>22</sup> Its recent development of CorVocet provides a good basis for the further development of the [name] devices which is part of the Divestment Business. This is particularly the case given that both [name] and CorVocet are [...] biopsy devices and share some technical similarities. The recent introduction of the CorVocet device also shows that Merit has relevant expertise in obtaining all required regulatory approvals for the launch of a biopsy device.
25. Given Merit's annual R&D budget of more than USD [...] and its recent launch of a [...] device, the Commission considers that Merit is capable of further developing and launching the [name] pipeline product.
26. While Merit is currently not active in the manufacturing of tissue markers, it can rely on its experience developing and bringing new products to the market and its important budget for R&D projects. Merit has expressed an interest in entering this market which is adjacent to the biopsy devices, in order to offer customers a broader portfolio.
27. In light of the above, the Commission concludes that Merit has proven expertise in the interventional radiology area, R&D, manufacturing, regulatory, logistics finance, marketing and sales and IT administration capabilities and the incentive to maintain and develop the Divestment Business.

*The capability to cover at least 80% of BD's current sales*

28. The purchaser criteria specify that a suitable buyer of the Divestment Business must have the capability, either directly or through third parties, to cover at least 80% of BD's current sales in the EEA. Currently, all of BD's sales are made via third party distributors.
29. Merit already serves customers of medical devices in the EEA. It operates a European distribution centre in the Netherlands<sup>23</sup> that handles more than 600 shipments per day to European customers. Existing relationships with current customers (mainly hospitals and clinics) can likely be leveraged for the commercialisation of the CNB biopsy devices and the pipeline products included in the Divestment Business. This includes direct sales capabilities as well as existing distribution agreements.

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<sup>20</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.1.5.

<sup>21</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 1.3.2.

<sup>22</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 3.3.

<sup>23</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 3.4.

30. Currently, Merit has a sales force of [...] people in the EEA, [...] of whom are dedicated to the Peripheral Intervention Division into which the new product lines will be integrated.<sup>24</sup> Merit's sales force is already familiar with biopsy devices, given the recent launch of the CorVocet device. However, it also has concrete plans to expand its sales force in the EEA with [...] clinical education experts, [...] sales representatives and [...] marketing product managers to support the portfolio of the Divestment Business.<sup>25</sup> In addition, Merit has existing relations with [...] distributors serving EEA countries<sup>26</sup> and intends to take over the existing contractual agreements of BD with its distributors in the EEA as regards the Divestment Business.
31. The Trustee has assessed the current hybrid distribution model of Merit and came to the conclusion that even in the unlikely situation that distributors do not agree to continue existing relationships in relation to the Divestment Business, Merit could replicate these sales directly or through its current distributors. This conclusion is based on the fact that Merit has particularly strong sales forces in the EEA countries where the large majority of sales are generated, namely the UK, France, Germany, and Spain. The Trustee therefore sees only little risk that the Divestment Business would not be successful under Merit's ownership.<sup>27</sup>
32. As regards the transition period, it has to be taken into account that the Proposed Agreements include provisions on bridge inventory to ensure an uninterrupted supply of customers.
33. In light of the above, the Commission concludes that Merit fulfils the purchaser criterion of being able to cover at least 80% of BD's current sales in the EEA.

*Incentive to maintain and develop the Divestment Business as a viable and active competitive force*

34. Merit has committed to pay a purchasing price of USD [...] to BD for the acquisition of the Divestment Business, showing a genuine economic interest to maintain and develop it.<sup>28</sup>
35. The CNB devices as well as the pipeline products in which the Divestment Business consists are complementary to Merit's current product portfolio and would extend its current offering. Merit also has the required manufacturing and sales capabilities available to integrate the Divestment Business into its existing production facilities as well as marketing and sales structures.
36. The Trustee has concluded that the Divestment Business would fit well into Merit's existing product portfolio and sales organisation and that Merit has the relevant incentives to maintain and further grow the Divestment Business. The target customers of the Divestment Business are also target customers of

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<sup>24</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 3.4.

<sup>25</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.2.2.

<sup>26</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 3.4.

<sup>27</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.1.9.

<sup>28</sup> Asset Purchase Agreement by and between Merit Medical Systems, Inc. and Becton, Dickinson and Company dated as of 15 November 2017, article 2.1.



Merit's existing business; and Merit has convincingly demonstrated that it intends to scale up the sales of BD's CNB devices in the EEA by leveraging its existing sales organisation. This is reflected in the business plan presented by Merit that assumes an annual increase in total sales once the transition is completed.<sup>29</sup>

37. In light of the above, the Commission concludes that Merit has the incentive to maintain and further develop the Divestment Business as a viable and active force in competition with the Parties and other competitors.

**(c) Absence of *prima facie* competition problems**

38. The acquisition of the Divestment Business by Merit is *prima facie* not likely to give rise to competition concerns. Merit currently has a limited CNB offering. The only overlap with the CNB product lines to be divested is the CorVocet device, which is a fully automatic biopsy device that provides a full core sample. It was only released on a limited basis in 2016 to select customers. Its current market presence is therefore limited with only USD [...] sales in the EEA in the 2017 year to date.<sup>30</sup>
39. The CorVocet device is a full core automatic device that cuts the tissue sample with a different type of technology than the "side-notch" technology utilised by the product lines of the Divestment Business. None of the CNB devices included in the Divestment Business can take a full core sample, which is an important factor distinguishing soft tissue biopsy devices.<sup>31</sup> Moreover, the portfolio of Merit is currently limited in this area, not offering manual or semi-automatic devices.
40. In addition, CorVocet is designed to take smaller samples and particularly focussed on liver biopsies. It therefore appears to rather complement than directly compete with the product range of the Divestment Business. At least these devices do not appear to be closely competing.
41. In relation to pipeline projects, Merit has been working on a [...] soft tissue biopsy device and an innovative [...] device which are still under development. The Trustee has reviewed the current development stage of the [...] biopsy device and came to the conclusion that Merit's pipeline device offers some features that differentiate it from existing [...] devices included in the Divestment Business (in particular BD's "[name]" product range). The pipeline device offers in particular [...]. In light of these additional features, the Trustee came to the conclusion that Merit's [...] pipeline product would rather complement the Divestment Business as a possible line extension to the [name] product range than become a directly competing product.<sup>32</sup>
42. As regards the [...] biopsy device under development by Merit, it seems plausible that this may bring synergies with the [name] pipeline product because both systems work with [...] technology. However, while Merit's

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<sup>29</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 6.2.3.

<sup>30</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 7.1.

<sup>31</sup> The Decision paragraph 39 and Replies to questionnaire Q2 – customers, question 5.

<sup>32</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 7.2.1.

pipeline design is a biopsy device that is inserted manually into the lesion and then cuts a sample [...], the [name] design is designed to [...]. Moreover, while Merit's pipeline design seems to target primarily [...] biopsies, the [name] device is developed specifically for [...] biopsy procedures. Therefore, both products are likely to be complementary in spite of the fact that synergies in relation to the technology development may exist.<sup>33</sup>

43. Merit does not have any commercialised or pipeline products in the area of tissue markers.<sup>34</sup> Therefore, it is also unlikely that competition concerns would arise in relation to project "[name]".
44. On the basis of the above, the Commission considers, in line with the Trustee, that the acquisition of the Divestment Business by Merit does not give rise to *prima facie* competition concerns.
45. This *prima facie* assessment is based on the information available for the purpose of this buyer approval and does not prejudice the competition assessment of the acquisition of the Divestment Business by Merit by a competent competition authority under applicable merger control rules.

## II.2 Divestment business is being sold in a manner consistent with the Commitments

46. The Commission has reviewed the Proposed Agreements and suggested a clarification of the definitions in the APA to ensure compliance with the Commitments, in particular relating to confidential know-how and additional information related to the Product Lines and the pipeline projects to be divested. In particular, the Commission emphasised that "books and records" relating to the product lines and pipeline projects shall include also all clinical trial results, regulatory documentation, clinical data, prototypes, and other documentation as defined in the Commitments as confidential know-how in paragraph 3(f) of the Schedule attached to the Commitments.
47. The Parties have agreed to take the concern into account and clarify the correct interpretation of the respective parts of the Agreements in a confirmation letter of 1 December 2017. This letter has been reviewed by the Trustee who came to the conclusion that the corresponding confirmation ensures that the Agreements are interpreted in line with the Commitments.
48. The Commission has also reviewed BD's confirmation letter 1 December 2017 and agrees that the confirmations given ensure the correct interpretation of the Agreements in light of the Commitments.
49. Taking into account the clarification given in BD's letter of 1 December 2017 and the Trustee's assessment, the Commission concludes that the Proposed Agreements ensure that the Divestment Business is being sold in a manner consistent with the Commitments.

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<sup>33</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 7.2.1.

<sup>34</sup> Monitoring Trustee Reasoned Opinion on Merit Medical of 1 December 2017, Section 7.2.2.

### III. CONCLUSION

50. On the basis of the above assessment, the Commission approves Merit as a suitable purchaser.
51. On the basis of the Proposed Agreements interpreted in light of the supplementary confirmation given by BD in its letter dated from 1 December 2017, the Commission further concludes that the Divestment Business is being sold in a manner consistent with the Commitments.
52. This decision only constitutes approval of the proposed purchaser identified herein and of the Proposed Agreements. This decision does not constitute a confirmation that BD has complied with its Commitments.
53. This decision is based on Section D of the Commitments attached to the Decision.

*For the Commission*

*(Signed)*

*Johannes LAITENBERGER  
Director-General*