UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC., AND MEDTRONIC VASCULAR, INC.
Petitioners,

v.

TELEFLEX INNOVATIONS S.A.R.L.
Patent Owner.

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Case IPR2020-00129
Patent RE 45,380

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# PATENT OWNER'S RESPONSE TO PETITIONERS' MOTION TO EXCLUDE EVIDENCE

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Petitioner's Motion to Exclude Exhibit 2024 (Paper 111 ("MTE")) should be denied. The motion attempts to exclude a highly relevant, potentially case-dispositive business document on inconsequential grounds that, at best, could go to the weight of the evidence. No authority cited by Petitioner gives grounds to exclude Exhibit 2024. Substantial testimony and surrounding evidence support the authenticity of this regularly kept business record. From beginning to end, Petitioner's motion falls flat on exclusion and instead, only further exposes that Petitioner simply cannot overcome Patent Owner's overwhelming evidence that the GuideLiner patents were conceived and reduced to practice before Itou's priority date.

## I. Exhibit 2024 Is the August 24, 2005 Product Requirements Document Supporting that GuideLiner Rapid Exchange Had Been Tested and Shown to Work for its Intended Purpose by At Least That Date

At Vascular Solutions, Inc. ("VSI"), the Product Requirements document at Exhibit 2024 marked the beginning of the formal regulatory process, or design history process, for bringing the GuideLiner project to market. Ex-2119, ¶44; Ex-2039, ¶6. The document defined "the safety and performance requirements for the [VSI] GuideLiner (OTW) and rapid exchange (RX) guide catheter support system." Ex-2024, ¶1.1.

As VSI's founder, CEO, and GuideLiner RX inventor Howard Root explained, Exhibit 2024 would not have been drafted, and the formal regulatory

process that it signaled would not have begun, "if the rapid exchange GuideLiner had not been determined to work for its intended purpose." Ex-2118, ¶54. Indeed, it was VSI's business practice to only create the Product Requirements document after a product was "prototyped, thoroughly tested, and shown to work for its intended purpose." Ex-2039, ¶6; *see also* Ex-1926, ¶18 ("The document was made as a regular practice of developing a product at VSI and was maintained in the regular course of VSI's business on its network."). As that business practice was applied here, Exhibit 2024 was created after the April 2005 and July 2005 GuideLiner RX prototypes were built, tested, and shown to work for their intended purpose. Ex-2119, ¶21-22, 44; Ex-2039, ¶6. From the time this document was created on August 24, 2005 forward, VSI continued to refine GuideLiner RX prototypes for purposes of manufacturability and commercialization. Ex-2119, ¶44.

As shown on the face of the document, Exhibit 2024 is the first revision, "[p]re-release" of this document, not the final Product Requirements document for the product. Ex-2024 at 4 ("Rev. 01" and "Pre-release"). The August 24, 2005 date of this document is consistent throughout, twice on the first page of the document, and again on the last. *Id.*, at 1, 4. It is also consistently labeled as "Rev. 01" in the top right-hand corner of each of the document's four pages. *Id.*, at 1-4.

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