PHILIPS

18. May 2022

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Docket No. FDA-2021-N-0507
Medical Devices: Quality System Regulations Amendments

Philips appreciates the opportunity to comment on Docket No. FDA-2-21-N-0507, Medical Devices: Quality System Regulations Amendments, and the Food and Drug Administration's ("FDA's" or "Agency's") efforts to promote transparency and to provide an opportunity for broad public input.

First and foremost, Philips strongly supports the proposed transition of the current US FDA 21 CFR Part 820 Quality System Regulation to the Quality Management System Regulation through incorporation of the International Standardization Organization (ISO) 13485 Quality Management System for Medical Devices. We applaud FDA in their approach, by proposing use of the international consensus standard without modification it provides an excellent example to global community. Setting the stage for how to incorporate linkages to existing national requirements without changing the standard or adding additional requirements. Thank you to all at the FDA who worked on this wording and approach towards globalization.

Philips does support the general industry position that there be a minimum two-year transition to ISO 13485 and requests that FDA provide clear guidelines on when this transition begins.

Please refer to the attached table regarding specific comments. If you have any questions, please feel free to reach out to me directly at my email: elisabeth.george@philips.com

Respectfully,

Elisabeth M. George

Elisabeth M. George
Philips
Head of Global Regulations and Standards