ANNEX A

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. The Medicines and Healthcare Products Regulatory Agency** **2. NHS Improvement**
1	**CORONER** I am David Clark Horsley, senior Coroner for the Coroner area of Portsmouth and South East Hampshire.
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On 21 May 2018 I commenced an investigation into the death of Ronald CLARK age 64. The investigation concluded at the end of the inquest on 15 February 2019. The conclusion of the inquest was cause of death: 1a. Multi-organ Failure, 1b. Necrotising Pancreatitis, 2. Chronic Obstructive Pulmonary Disease. Ronald CLARK died due to an Accident.
4	**CIRCUMSTANCES OF THE DEATH** On the Nineteenth January 2018 Ronald CLARK underwent the insertion of a stent in his common hepatic duct. The incorrect sized stent was inadvertently inserted and this, on the balance of probabilities, significantly contributed to his death at Queen Alexandra Hospital, Portsmouth on Second of April 2018.
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – 1. I was told in evidence that the stents used at the hospital are all supplied in identical packaging with only a small label identifying the size of the stents inside. I was also told that stents in this sort of packaging are in general use in most, if not all, NHS hospitals. 2. I believe action should be taken by the purchasing agencies of the NHS to ensure that stent manufacturers should supply different sizes of stents in different coloured packaging to make it easier for them to be identified during medical procedures and to obviate the risk of the wrong-sized stent being used, as was the case with Mr Clark.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe your organisation have the power to take such action.

7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 4th June 2019. I, the Coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the Chief Coroner and to the following Interested Persons Mr Clarks family and Queen Alexandra Hospital, Portsmouth. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**08 April 2019** **David Clark Horsley**